

VA



U.S. Department of Veterans Affairs

Veterans Health Administration

State of Care for Veterans with Hepatitis C 2014

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State of Care for Veterans with Hepatitis C 2014

U.S. Department of Veterans Affairs

**Veterans Health Administration
Office of Public Health/Clinical Public Health
HIV, Hepatitis, and Public Health Pathogens Programs
VA National Viral Hepatitis Program**

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Preface

Chronic hepatitis C virus (HCV) infection is the most common blood-borne infection in the United States (U.S.) Department of Veterans Affairs (VA), the U.S., and the world. Complications that result from untreated HCV infection include progressive liver damage leading to cirrhosis, primary cancer of the liver, liver failure, and death. Although many of these complications are treatable or even preventable, three-quarters of the individuals with HCV infection¹ in the U.S. are unaware they are infected (Smith, et al. 2012).

In 2010, the U.S. Institute of Medicine (IOM) issued a groundbreaking report, *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control*, which projected that as many as 120,000 people in the U.S. will die of complications from HCV over the next decade (Institute of Medicine 2010). The IOM report proposed an evidence-based response to this epidemic, which was coordinated between Federal, state, and private stakeholders to address gaps in surveillance, education of patients and providers, prevention, treatment, and care of patients with HCV infection. In response to the IOM report, the U.S. Department of Health and Human Services (DHHS) released a national action plan for the prevention, care, and treatment of viral hepatitis, which was recently updated (United States Department of Health and Human Services 2014). As the largest HCV infection care provider in the nation, VA is proud to be a participating agency in this critical effort. The VA's National Viral Hepatitis Program (NVHP), part of the HIV, Hepatitis, and Public Health Pathogens Programs (HHPHP) within the Veterans Health Administration's (VHA) Office of Public Health/Clinical Public Health (OPH/CPH), is charged with leading the VA response to the HCV epidemic.

NVHP was established in 2001 to emphasize access to high-quality clinical care and prevention of HCV infection for Veterans in care within VHA through screening, counseling, patient and provider education, and evidence-based quality improvement. Program accomplishments include extensive screening of at-risk Veterans, early and broad access to direct-acting antiviral therapy, and improvements in the management of comorbidities such as depression, alcohol use disorders, and other substance use disorders.

In addition to providing excellent clinical care at the patient level, an effective response to the HCV epidemic in VHA demands a population health framework for organizing such care. A population health approach involves defining the group of affected Veterans, conducting surveillance on the population and relevant subgroups, and describing the epidemiology of HCV infection in these patients – their demographic characteristics, clinical comorbidities, and disease complications. These data allow analysis of key measures of access to and quality of care, as well as examination of trends in the evolution of the epidemic, identification of potential targets for improvement in care delivery, development of a plan to achieve such improvements, execution of the plan, and evaluation of its results.

As part of VHA's population health approach to the care of Veterans with HCV infection, OPH prepared a report in 2010 on the State of Care for Veterans with Hepatitis C. The report described the epidemiology of HCV infection in VHA and access to and quality of care provided to HCV-infected Veterans in care within VHA. It also discussed the trajectory of the HCV epidemic in VHA and initiatives to address the progression of the epidemic in VHA.

¹ Throughout this report, "HCV infection" refers to individuals with chronic infection (i.e., presence of HCV in the blood six months or more after initial exposure); it does not include individuals who were transiently infected by HCV but who permanently cleared the virus.

This second Hepatitis C State of Care report has been prepared by NVHP, in collaboration with the OPH/Population Health Program. This report describes the population of Veterans with HCV infection in VHA care (including comorbid conditions), assesses trends in complications of HCV infection among Veterans in VHA care, and examines access and quality of care metrics. The report includes VHA data from calendar years 2002 through 2013, derived from the VHA's Clinical Case Registry: HCV (CCR: HCV), the VHA's Corporate Data Warehouse (CDW), and the VHA Liver Disease Database (LDD). It is intended to support VHA clinicians, VHA facility leadership, and Veterans Integrated Service Network (VISN) leaders in their ongoing efforts to optimize the quality of care VHA provides our Nation's Veterans. In addition, it is intended to inform Veterans, their families, and other stakeholders about the state of care in VHA for Veterans with HCV infection.

We are grateful to OPH/Population Health Program and the staff of the VHA LDD unit for their critical assistance in producing this report. OPH/CPH staff members who were instrumental in the development of this report are listed in the Acknowledgements section.

We hope that this report contributes to the improvement of the clinical care VHA provides to HCV-infected Veterans, educates providers and policymakers about important clinical trends, and highlights the clinical impact of policy decisions. It also provides a framework for understanding the clinical import of the recent revolution in HCV antiviral therapy, and the clinical, programmatic, and policy challenges these changes pose to our health care system.

As this report demonstrates, VHA is committed to providing evidence-based care to ensure the continual improvement of VHA care for Veterans with HCV infection. It would not have been possible without the efforts of VHA staff located at VHA facilities across the U.S. This report is dedicated to them and to the Veterans whom we serve.

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Executive Summary

Chronic infection with hepatitis C virus (HCV) is a major public health problem in both the Veterans Health Administration (VHA) and the United States (U.S.), owing to the large number of affected individuals and the potential for progression to cirrhosis, hepatocellular carcinoma (HCC), and other life-threatening conditions. VHA is the single largest HCV infection care provider in the U.S., with an HCV infection prevalence of 4.0 percent among Veterans in VHA care (Dominitz, et al. 2005), which is more than three times that of the general U.S. population; VHA provided care for more than 170,000 Veterans with HCV infection in 2013. The majority of HCV-infected Veterans² are men 50-69 years of age living in urban areas, with African-American Veterans disproportionately affected by HCV infection. Veterans born between 1945 and 1965, those with comorbid alcohol or substance use disorders and psychiatric conditions, and those who are homeless are particularly likely to be affected. Among Veterans born between 1945 and 1965 (referred to as the 1945-65 birth cohort), 9.5% are infected with HCV, compared with 2.4% of the 1945-65 birth cohort in the general U.S. population (Smith, et al. 2012). The gradual progression of HCV infection among affected Veterans over a period of decades has led to increasing numbers of patients with cirrhosis and HCC. Over the past 12 years, the number of HCV-infected Veterans in VHA care diagnosed with cirrhosis has more than doubled to over 29,000 individuals, while during the same time period the cumulative number of HCV-infected Veterans diagnosed with HCC has increased nine-fold.

VHA is a leader in the U.S. in HCV infection care, including screening,³ treatment, and prevention. Between 2002 and 2013, the percentage of Veterans in VHA care with at least one outpatient visit who had ever received VHA screening for HCV infection doubled from 26.9% to 56.0%; in 2013, 65% of Veterans in the 1945-65 birth cohort had ever been screened for HCV infection. Similar striking improvements were seen in confirmatory testing after an initial positive screening result, which increased to 96% across the system by 2013. Marked improvements also have been achieved in quality-of-care measures such as rates of immunization, HIV screening, and HCC screening.

In the past three years, significant gains have been made in the therapeutic options available to cure HCV infection, with further gains expected in the near future. In 2011, two novel HCV medications – boceprevir and telaprevir – were approved by the U.S. Food and Drug Administration (FDA) for use in combination with pegylated interferon and ribavirin. They represented a major advance in HCV treatment, as they were the first new drugs approved in ten years for HCV treatment, and offered improved cure rates compared to previous therapies. In 2013, FDA approved two more antiviral medications for use as part of combination regimens – sofosbuvir and simeprevir – which offer shorter treatment durations and decreased side effects in addition to increased cure rates. Several other new agents and combinations of agents are expected to receive FDA approval in 2014-15, making additional treatment regimens available for patients. The evolution of management and treatment of HCV infection will make it possible to cure an increasing proportion of HCV-infected Veterans with fewer side effects. Amidst this optimistic projection, 35% of Veterans in the 1945-65 birth cohort in VHA care still require HCV screening, and increasing numbers of Veterans are developing cirrhosis and HCC.

² Unless otherwise indicated, throughout this report, the term “Veterans” refers to Veterans enrolled for health care in VHA.

³ Throughout this report, the term “screening” refers to initial laboratory testing for the presence of HCV infection, rather than assessment of risk factors for HCV infection.

VHA is committed to providing high-quality, compassionate, professional care to the nation's HCV-infected Veterans. It therefore undertakes both continual and periodic assessments at the local, regional, and national levels to evaluate the HCV infection care VHA provides. For more than a decade, HHPHP has used a variety of data sources to evaluate the spectrum and quality of HCV care according to evidence-based guidelines and treatment recommendations. Reports on patient volume, demographics, rates of common comorbidities, and selected quality indicators are routinely disseminated to all VHA HCV providers and posted internally for the broader VHA audience at <http://vawww.hepatitis.va.gov/data-reports/ccr-index.asp>. This State of Care report builds on that foundation and presents a summary view of care for Veterans with HCV infection over the past 12 years. This periodic overview allows VHA to proactively anticipate workforce, funding, and logistic needs, and prioritize areas for quality improvement.

This summary report provides a population view of VHA care for Veterans infected with HCV. It describes the demographic and clinical characteristics of HCV-infected Veterans and will help VHA anticipate the future clinical needs of Veterans and the infrastructure changes these needs require, facilitate decision-making regarding allocation of resources to maintain high-quality HCV care, and identify care processes and outcomes that can be improved. Most importantly, it highlights the growing burden and impact of HCV infection and its complications, and defines new opportunities to expand antiviral therapy and treatment of complications.

This State of Care report identifies areas of success, such as the exceptional rate of confirmatory testing after initial HCV screening. It also identifies areas for improvement, including reducing geographic variation in quality measures such as antiviral treatment rates and HIV screening. Important clinical trends, such as the increase in the incidence and prevalence of cirrhosis and HCC, are highlighted. These trends will command expanded health care resources and increase the complexity of medical care for affected Veterans. Further, these data may facilitate a detailed review of care delivery processes to identify barriers to high-quality care. Removing barriers can require policy changes, development or refinement of practice guidelines, system redesign, and development of tools for monitoring population health. HHPHP will continue to assess and address quality-of-care issues, monitor for emerging issues, and identify strategies to improve the quality of and access to care.

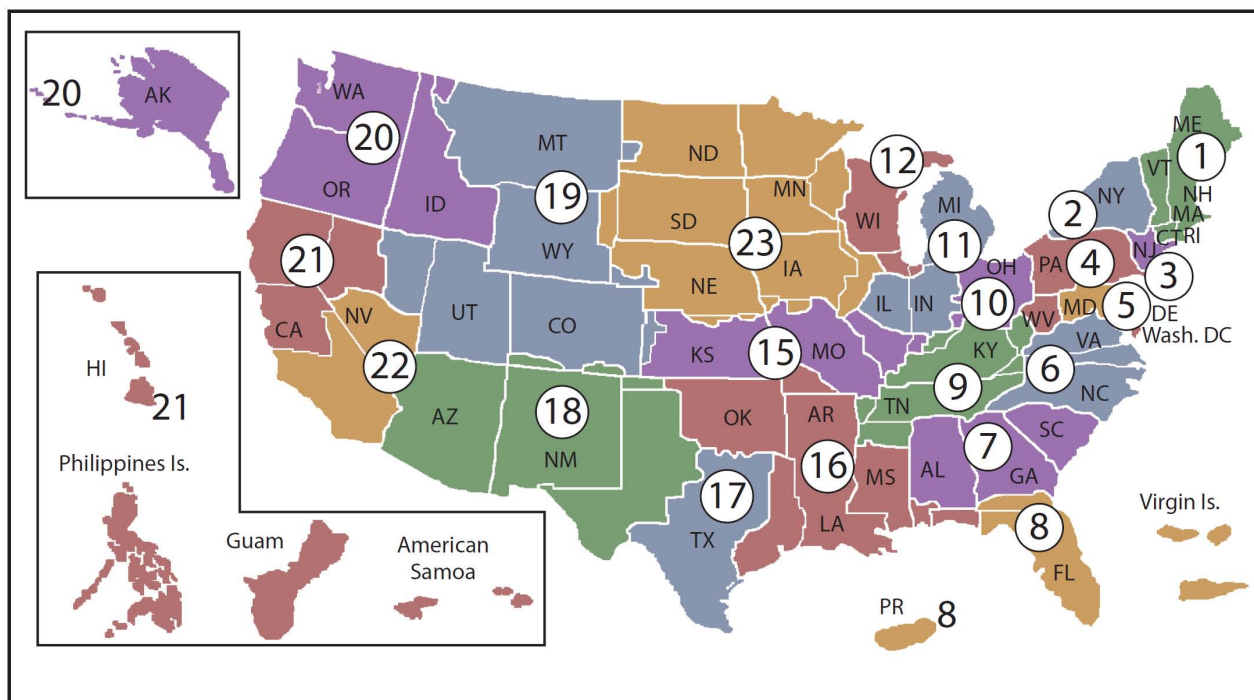
Chapter 1: Background and organizational structure

1.1 Department of Veterans Affairs, Veterans Health Administration

The Veterans Health Administration (VHA) of the Department of Veterans Affairs (VA) is a comprehensive Federal health care system serving eligible, enrolled Veterans who have served in the U.S. Armed Forces. VHA is the largest provider of integrated civilian health care within the U.S. It is organized into 21 geographically defined multistate regions called Veterans Integrated Service Networks (VISNs) (Figure 1). Each VISN oversees the administrative and clinical functions within its geographic area of operations. The 21 VISNs contain a total of 151 regional health care systems called Stations. Within each Station, there are numerous medical facilities, which include hospitals (VA Medical Centers, or VAMCs), community-based outpatient clinics, skilled nursing facilities, rehabilitation centers, hospices, and domiciliaries. There are over 1,200 VHA facilities in the U.S. and its territories.

In Federal fiscal year 2013, there were 8.9 million VHA enrollees. Nationwide, there were 694,700 admissions at VHA hospitals, and over 86.4 million outpatient visits at VHA facilities in that fiscal year. Additional information on the general Veteran population can be found at <http://www1.va.gov/vetdata/>.

Figure 1. The 21 VISNs of the VHA health care system



1.2 Overview of the VHA Office of Public Health

The mission of the VHA Office of Public Health (OPH), a Program Office within VHA Central Office, is to serve as the leader and authority in public health, a core element of VHA's ability to fulfill its mission to serve and honor the men and women who are America's Veterans. Within VHA, public health is defined as the science and practice of promoting health and preventing disease among Veteran and VHA staff populations. In this context, health can be affected by natural or human-made environments, present and past occupations, place in society, gender, and other social or individual characteristics.

OPH's mission is reflected in four pillars that uphold the ideals, initiatives, services, and programs within the office. They are 1) surveillance and epidemiology; 2) focus on underserved populations; 3) disease prevention, risk reduction, and health promotion; and 4) public health policy and guidance. The VHA approach to HCV infection in Veterans is organized around these four pillars. OPH also manages the VHA public health response to emergencies and protects the safety and health of VHA employees. Additional information is available at www.publichealth.va.gov.

1.2.1 Clinical Public Health

Clinical Public Health (CPH) is an organizational unit within OPH. CPH's mission is to improve the health of Veterans through the development of sound policies and programs related to several major public health concerns including: HCV infection, human immunodeficiency virus (HIV) infection, influenza, smoking and tobacco use, and emerging infections of public health significance, such as health care-associated infections. CPH strives to promote the highest-quality, comprehensive care for Veterans and to have that care recognized as the standard by which all health care in the U.S. is measured. CPH's efforts include fostering high-quality patient care, clinician education, patient education, prevention activities, policy development, and operational research directed at continuous improvement of medical and preventive services delivered to Veterans. Additional information on CPH is available at <http://www.publichealth.va.gov/about/pubhealth/index.asp>.

1.2.2 HIV, Hepatitis, and Public Health Pathogens Program

The HIV, Hepatitis, and Public Health Pathogens Program (HHPHP), a unit within CPH, has the mission of providing state-of-the-art clinical public health services in the areas of HIV, viral hepatitis, and public health pathogens. Within HHPHP, VHA's National Viral Hepatitis Program (NVHP) guides HCV infection care. In addition to developing national policy on HCV infection care within VHA, it analyzes the quality of HCV infection care in VHA, identifies and disseminates evidence-based quality improvement interventions, facilitates Veteran and provider input on the provision of HCV infection-related health care and policies, coordinates training and educational programs to advance excellence in HCV care, and monitors trends in HCV infection prevalence and its clinical sequelae. NVHP advocates for Veterans with HCV infection and the VHA clinical providers who serve them. To carry out its mission, NVHP collaborates with multiple stakeholders within VHA, such as the Office of Public Health/Population Health, the National Center for Health Promotion and Disease Prevention (NCP), the Office of Specialty Care, the Primary Care Office, the Quality Enhancement and Research Initiative – HIV/HCV (QUERI – HIV/HCV) and others. It also collaborates with non-VHA stakeholders, such as the U.S. Centers for Disease Control and Prevention (CDC), professional societies, and HCV patient advocates. The NVHP's goal is for patients with or at risk of HCV infection to receive the highest-quality health care services. Led by HHPHP and carried out

by providers at VHA medical facilities across the country, the program takes a comprehensive approach to HCV infection that includes:

- Promotion of screening for HCV infection
- Education about HCV infection for patients and their families
- Prevention and harm reduction activities
- Clinician training on state-of-the-art management and treatment of HCV
- Promotion of excellence in clinical care
- Proactive operational research to improve clinical care
- Data-driven quality improvement

1.2.3 Population Health

Within OPH, the Population Health unit performs the mission of reporting on the health and health needs of America's Veterans. To accomplish this mission, the group measures, monitors, and identifies trends that impact the health of all Veterans. Population Health maintains the VHA's National Clinical Case Registry for HCV (CCR: HCV) infection. This work is possible because of VHA's electronic health record (EHR). Taking advantage of clinical data from VHA's EHR, Population Health develops centralized patient registries, and enhances local registry functions to provide clinicians with useful information about their populations of Veterans with HCV. Population Health staff members provide support to VHA clinicians and administrative staff to enhance their ability to use the CCR. Population Health also provides other electronic tools such as optional Clinical Reminders.

1.3 Data sources and interpretation of data

HHPHP obtained data from multiple sources to compile this report. The majority of the data was drawn from VHA's CCR: HCV and Corporate Data Warehouse (CDW) through the Office of Public Health/Population Health. Additional data were drawn from the CDW through the Liver Disease Database (LDD) unit. Data obtained through the Clinical Case Registry: HCV cover the period 2002-13, whereas data obtained through the LDD cover the period spanning 2002-12.

1.3.1 Clinical Case Registry: HCV

The CCR: HCV (Backus, et al. 2009) is a national database of HCV-infected Veterans in the U.S. receiving medical care at any VHA facility. CCR: HCV coordinators at VHA medical centers manually verify all new diagnoses of HCV infection (using serology results, viral load results, and ICD-9 diagnoses). After confirmation of HCV infection, clinical, laboratory, and administrative data on patients at each local VHA medical facility are electronically transmitted nightly to the national CCR: HCV using secure HL7 messaging.

Unless otherwise noted, results in this report are produced from the national CCR: HCV and reflect the state of care nationwide for Veterans in care in a given calendar year⁴ who have

⁴ "In care" is defined as having had one outpatient visit, one outpatient prescription filled, or one inpatient stay at a VHA facility during the target calendar year.

ever been HCV viremic.⁵ More information about the CCR: HCV is available at <http://vaww.vistau.med.va.gov/VistaU/ccr/default.htm>. More detailed information about the construction of measures used in this report as well as Station-level data for 2013 is available at <http://vaww.hepatitis.va.gov/data-reports/ccr-index.asp>.

1.3.2 Corporate Data Warehouse

The VHA CDW is a national relational database comprising data from several VHA clinical and administrative systems. The VHA EHR system is the primary source of data for the CDW; the CDW is dynamically updated from the EHR. Additional sources of CDW data include the National Patient Care Database, the Compensation and Pension Exam Database, the VHA Decision Support System, and MyHealtheVet, the VHA personal health records system. The CDW includes demographic information, health care utilization data, ICD-9 diagnostic codes, and CPT-4 procedural codes. The CDW includes VHA laboratory data from October 1, 1999. More information about the CDW is available at <http://vaww.virec.research.va.gov/CDW/Overview.htm>.

1.3.3 Liver Disease Database

The VHA Liver Disease Database (LDD) unit supports HHPHP by providing epidemiologic data related to advanced liver disease. Advanced liver disease status is defined using two outpatient liver-related ICD-9 codes occurring on separate days or one inpatient liver-related ICD-9 code. The LDD supports multiple quality improvement initiatives to promote high-quality liver care. The LDD was originally composed of a series of static extracts from medical and Decision Support System Statistical Analysis System files in the VA Austin Information Technology Center. Since June 2012, LDD data have been extracted from the CDW. Comparison of the LDD cohort between Austin files and the CDW demonstrates similar counts of cirrhotic patients with a mean difference of 6.4% for each year. This small difference is explained by the dynamic nature of the CDW, in which data elements are constantly updated, unlike the static data extracts. At the time that this report was written, LDD data were available through 2012. LDD variables are fully linkable to other VHA data sources in the CDW, including diagnosis codes and problem lists, prescriptions, procedures, laboratory tests, radiology exams, patient demographics, hospital admissions, and clinic visits. More information about the LDD is available at <http://vaww.hepatitis.va.gov/data-reports/ldd/index.asp>.

⁵ "Viremic" individuals are individuals with VHA laboratory documentation of HCV in their blood. HCV viremic Veterans in care includes Veterans who had detectable HCV virus in their blood and who have achieved cure (sustained viral response) after HCV antiviral therapy, those who have spontaneously cleared the virus, and those who still have ongoing infection. At the time of this report, the overwhelming majority of HCV viremic Veterans still have ongoing infection. This report does not analyze Veterans who have evidence of prior exposure to HCV (i.e., who are HCV antibody positive) but who do not have VHA laboratory evidence of HCV viremia, either because no VHA test for viremia was performed or because the patient had spontaneously cleared the virus prior to entry into VHA care.

Chapter 2: Veterans with hepatitis C virus infection

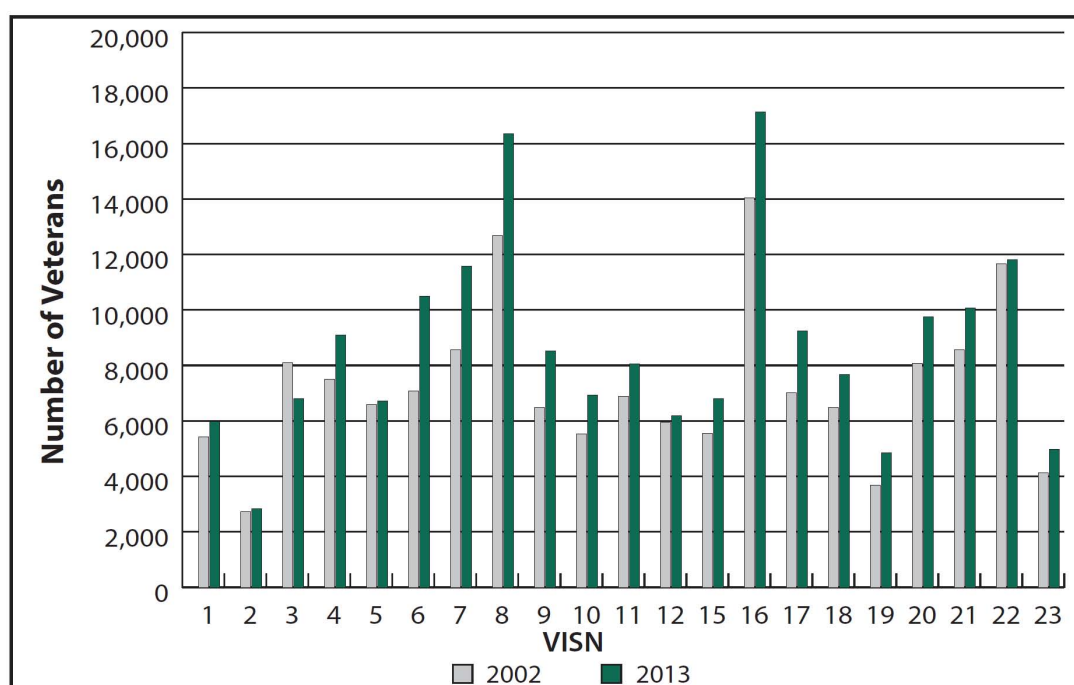
Veterans infected with HCV in VHA care receive primary care through their local VHA community-based outpatient clinic or VHA medical center. Veterans may need to travel to another VHA facility within their Station to receive the full spectrum of specialized HCV care. In some cases they must travel to a facility outside their Station for services such as liver transplantation. Increasingly, telemedicine platforms (telehealth and Specialty Care Access Network-Extension for Community Outcomes (SCAN-ECHO)) are being used to deliver care to Veterans in remote areas or to Veterans with conditions that limit mobility.

2.1 Patients in care

Of the 4,249,138 Veterans nationwide with at least one outpatient visit in 2002, 146,290 (3.4%) had VHA laboratory documentation of HCV viremia. In 2013, of the 5,595,605 Veterans in VHA care with at least one outpatient visit during the calendar year, 174,302 (3.1%) Veterans had documented hepatitis C viremia, an absolute numerical increase of 19% over the 12-year period. Increases in the number of HCV viremic patients were seen across all but one VISN, with the greatest increases seen in VISNs 8 and 6 (Figure 2). As most Veterans with HCV infection were infected decades ago (Wasley, et al. 2008), and as there are fewer than 20,000 new HCV infections in the U.S. every year, the increase in the number of HCV-infected Veterans in VHA care largely represents screening and identification of individuals with pre-existing HCV infection rather than new infections. Entry of previously diagnosed patients into VHA care may also have contributed to this increase.

Overall, among 3,120,303 Veterans with at least one outpatient visit in 2013 and an informative HCV test result obtained at any time, 5.8% were HCV infected. In the 1945-65 birth cohort, 9.5% were HCV-infected. In comparison, 2.4% of the 1945-65 birth cohort in the general U.S. population is estimated to be HCV infected (Smith, et al. 2012). It is important to remember that the cohort of HCV-infected Veterans in VHA care changes from year to year due to new diagnoses, deaths, and Veterans with HCV infection moving into or out of VHA care.

Figure 2. Number of HCV viremic Veterans in care by VISN: 2002 and 2013



2.2 Demographics

2.2.1 Sex

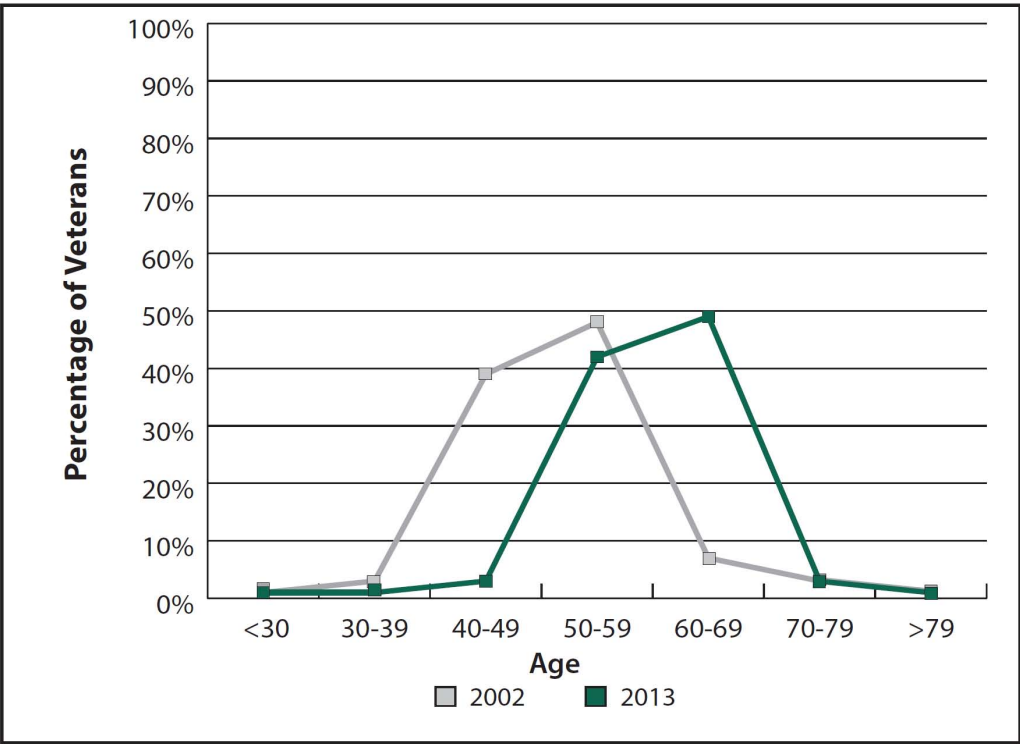
There was no change between 2002 and 2013 in the distribution of cases by sex. Across the 12-year period, 97% of HCV viremic Veterans in care were male, while 3% were female. The distribution of HCV cases by sex is similar to the overall distribution among all Veterans who had at least one outpatient visit in the calendar year (93% of whom are male).

2.2.2 Age

The population of Veterans affected by HCV is aging. Older Veterans are more likely to have comorbidities that may limit administration of antiviral therapy. In addition, the risk of developing cirrhosis increases both with increased duration of HCV infection and increased age.

In 2002, the mean age of HCV-infected Veterans was 51 years; by 2013, the mean age had risen to 59.7 years. The shift in the age distribution of VHA HCV patients between 2002 and 2013 is shown in Figure 3. Of note, in 2013, 81.1% (6,324) of the 7,794 Veterans entered for the first time into the CCR: HCV (representing new diagnoses as well as patients with established diagnoses transferring care to VHA) were 50-69 years of age.

Figure 3. Age distribution of HCV viremic Veterans in care: 2002 and 2013



2.2.3 Race and ethnicity

The racial and ethnic distribution of HCV viremic Veterans has not changed substantially between 2002 and 2013 (Table 1 and Table 2). HCV infection continues to disproportionately affect African-American Veterans; in 2013, only 15.4% of Veterans in care were African-American, yet 34% of HCV viremic Veterans in care were African-American. Because VHA data on race and ethnicity of individual patients are often self-reported and incomplete, these proportions should not be regarded as definitive.

Table 1. Race of HCV viremic Veterans in care: 2002 and 2013

	White	African-American	Multiracial	Asian	Native Hawaiian or Pacific Islander	Unknown
2002	48%	33%	1%	<1%	<1%	17%
2013	54%	34%	<1%	<1%	<1%	9%

Table 2. Ethnicity of HCV viremic Veterans in care: 2002 and 2013

	Not Hispanic or Latino	Hispanic or Latino	Unknown
2002	81%	6%	14%
2013	89%	6%	5%

2.2.4 Homelessness

HCV infection is of particular importance among homeless Veterans. Depending on the sample selection process, it is estimated that 9.9% to 44% of homeless Veterans have antibodies to HCV or are infected with HCV (Dominitz, et al. 2005; Cheung, et al. 2002; Desai, et al. 2003). Homelessness is a significant impediment to the receipt of medical care, and often impairs a Veteran's ability to receive or complete antiviral treatment. Many homeless Veterans have comorbid substance use disorders (e.g., alcoholism or injection drug use), which may hasten the progression of liver disease (in the case of alcohol consumption (Ghany, et al. 2009)) or place the Veteran at risk of recurrent HCV infection (in the case of injection drug use (Aspinall, et al. 2013)).

2.2.5 Geographic location of Veteran residence

Ensuring equity in patient access to care regardless of geographic location is a key goal for VHA. In the decade between 2002 and 2012, there was little change in the proportion of HCV-infected Veterans who lived in urban, rural, or highly rural areas. In 2002, 74% of Veterans in care with HCV infection lived in an urban area, 25% lived in a rural area, and 1% lived in a highly rural area. This compares with 2012, when 73%, 27%, and 1% of Veterans lived in urban, rural, and highly rural areas, respectively.⁶ In 2012, VISN 23 had the highest percentage of Veterans in care with HCV who resided in a rural or highly rural area (45%), while VISN 3 had the lowest percentage (6%). In 2012,

⁶ Data regarding the geographic residence of Veterans were provided by the LDD using the CDW. In 2002, data about the geographic distribution of Veteran residence were available for 65% of Veterans. For the 2012 report, data about the geographic distribution of Veteran residence were available for 98% of Veterans. The residential address used was the one on file as of December 2013. The VA Office of Rural Health's definitions of urban, rural, and highly rural were used for this analysis. An "urban" area is a Census Bureau-defined urbanized area, a "rural" area is any non-urban or non-highly rural area, and a "highly rural" area is any area in counties having <7 civilians per square mile. Please see <http://www.ruralhealth.va.gov/about/rural-veterans.asp> for further details.

VISN 19 had the largest percentage of Veterans in care with HCV who were residing in highly rural areas (9%). Rural residence can potentially complicate Veterans' access to HCV antiviral therapy and impede quality care for comorbid medical conditions, including substance use and mental health conditions. One study has found that Veterans residing in rural or highly rural areas were less likely to access HCV specialty care than Veterans residing in urban areas, although results for quality indicators were mixed; for example, rural and highly rural Veterans were more likely to receive antiviral medications (Rongey, et al. 2013). Additional analyses are warranted to determine whether geographic location affects access to and quality of HCV care in VHA and what interventions are required to improve equity.

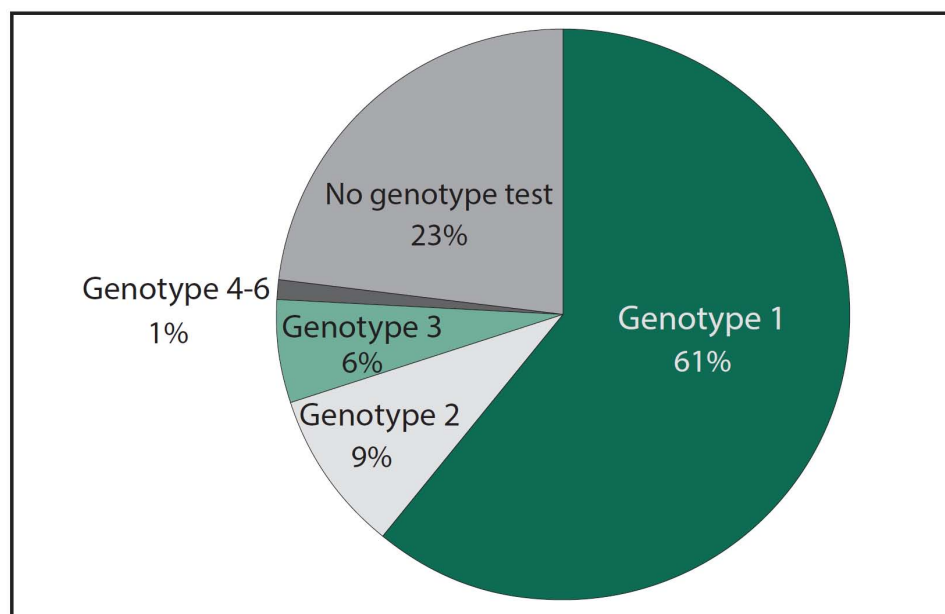
2.2.6 Operation Enduring Freedom (OEF)/Operation Iraqi Freedom (OIF)/Operation New Dawn (OND) Veterans

In 2002, 80 OEF/OIF/OND Veterans in VHA care were known to be HCV viremic. This increased to 1,605 Veterans in 2013. Forty-nine percent of these patients were located in six VISNs: VISN 1 (126 of 5,981 viremic patients), VISN 4 (148 of 9,098 viremic patients), VISN 7 (105 of 11,576 viremic patients), VISN 8 (140 of 16,362 viremic patients), VISN 9 (190 of 8,514 viremic patients), and VISN 16 (134 of 17,145 viremic patients).

2.2.7 Distribution of hepatitis C virus genotypes

The distribution of genotypes among VHA HCV-monoinfected⁷ patients in VHA care in 2013 is shown in Figure 4. Approximately 60% (103,298) of HCV viremic Veterans had genotype 1 infection. Of note, almost a quarter (39,633) of HCV-infected Veterans in VHA care in 2013 had not had a genotype determined. Historically, infection due to genotype 1 (relative to other genotypes) has been more difficult to cure using antiviral therapy with pegylated interferon and ribavirin. With the newer antiviral therapies, a smaller difference in cure rates between infections due to different genotypes is expected.

Figure 4. Distribution of HCV genotypes among HCV viremic Veterans in care: 2013



⁷ "Monoinfected" refers to Veterans chronically infected only with HCV, but not with HIV or hepatitis B virus. See Sections 2.3.1 and 2.3.2 for discussion of Veterans coinfecting with HCV and HIV or hepatitis B virus.

2.3 Comorbid medical, mental health, and substance use conditions

Comorbid conditions⁸ and clinical sequelae of HCV infection affect the complexity of clinical decision-making, candidacy for antiviral therapy, clinical outcomes, the cost of care, and resource allocation needed for quality care.

2.3.1 Comorbid HIV infection

Between 2002 and 2013, the absolute number of HCV viremic Veterans in care who were coinfecting with HIV decreased slightly from 6,184 (4.2% of HCV viremic Veterans) to 5,733 (3.3% of HCV viremic Veterans). Identification of HIV/HCV coinfecting Veterans is impacted by variability in HIV testing rates among HCV viremic patients across the system, potentially leading to underdiagnosis of HIV/HCV coinfection (see Chapter 4.7). It is important to identify HCV-infected Veterans who also are infected with HIV, as coinfection with HIV is associated with faster progression of hepatic fibrosis (Sulkowski, et al. 2007; Macias, et al. 2009).

2.3.2 Comorbid hepatitis B virus infection

Between 2002 and 2013, the number of HCV viremic Veterans in care who had ever been coinfecting with hepatitis B virus increased 22% from 10,011 to 12,233 individuals, but the percentage remained unchanged at 7% due to the increase in the total number of HCV viremic patients in VHA care. Again, because of variability in hepatitis B virus screening rates, coinfection with hepatitis B virus and HCV may be underdiagnosed among Veterans in VHA care.

2.3.3 Comorbid mental health conditions

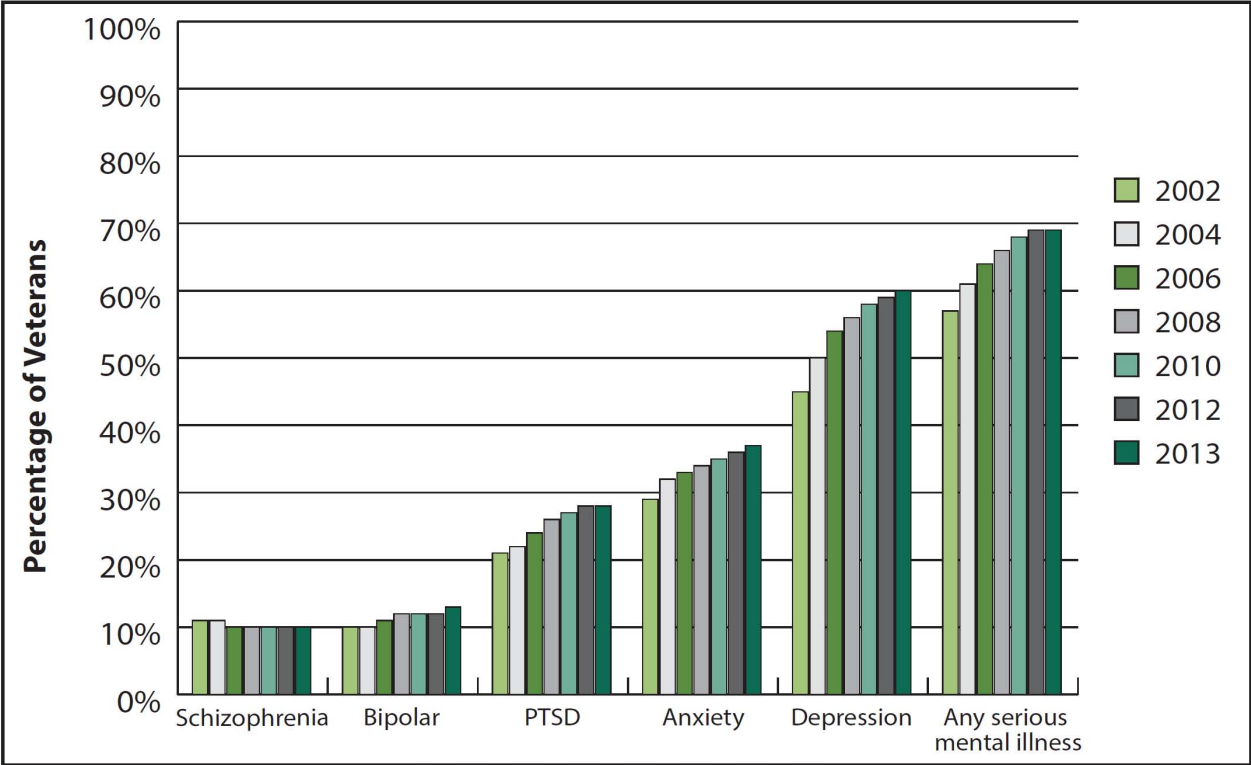
Comorbid mental health conditions have important implications for HCV-infected Veterans. Severe depression precludes the use of interferon, which has been the backbone of HCV treatment, and may remain an important component of antiviral regimens for many patients through 2015. In addition, active mental health conditions often limit treatment candidacy if clinicians determine that the mental health condition may decrease medication adherence or adherence to general medical care.

Given the 19% increase in the number of HCV-infected Veterans in care from 2002 to 2013, there was a disproportionate increase in the percent of HCV-infected Veterans with a history of mental health diagnoses (Figure 5). The proportion of Veterans with HCV infection who had ever received a diagnosis of post-traumatic stress disorder (PTSD) increased 33%, of depression increased 33%, of bipolar disorder increased 30%, of anxiety disorder increased 28% and of any serious mental illness⁹ increased 21%. The proportion that had ever received a diagnosis of schizophrenia decreased slightly from 11% to 10% across the 12-year period. Although these data do not allow an analysis of the reasons for these increases, substantial efforts over the past decade to promote screening of Veterans for mental health conditions, particularly depression and PTSD, likely account for a significant portion of this increase.

⁸ Unless otherwise identified in the text, comorbid diagnoses were defined using ICD-9 codes.

⁹ "Serious mental illness" is defined by the Public Health Service Act as a mental behavioral or emotional disorder of sufficient duration to meet applicable diagnostic criteria and which results in functional impairment interfering with one or more life activities. For purposes of this report, serious mental illness is any of the following diagnoses: schizophrenia, bipolar disorder, PTSD, anxiety, or depression.

Figure 5. National trends in mental health diagnoses among HCV viremic Veterans in care: 2002-13

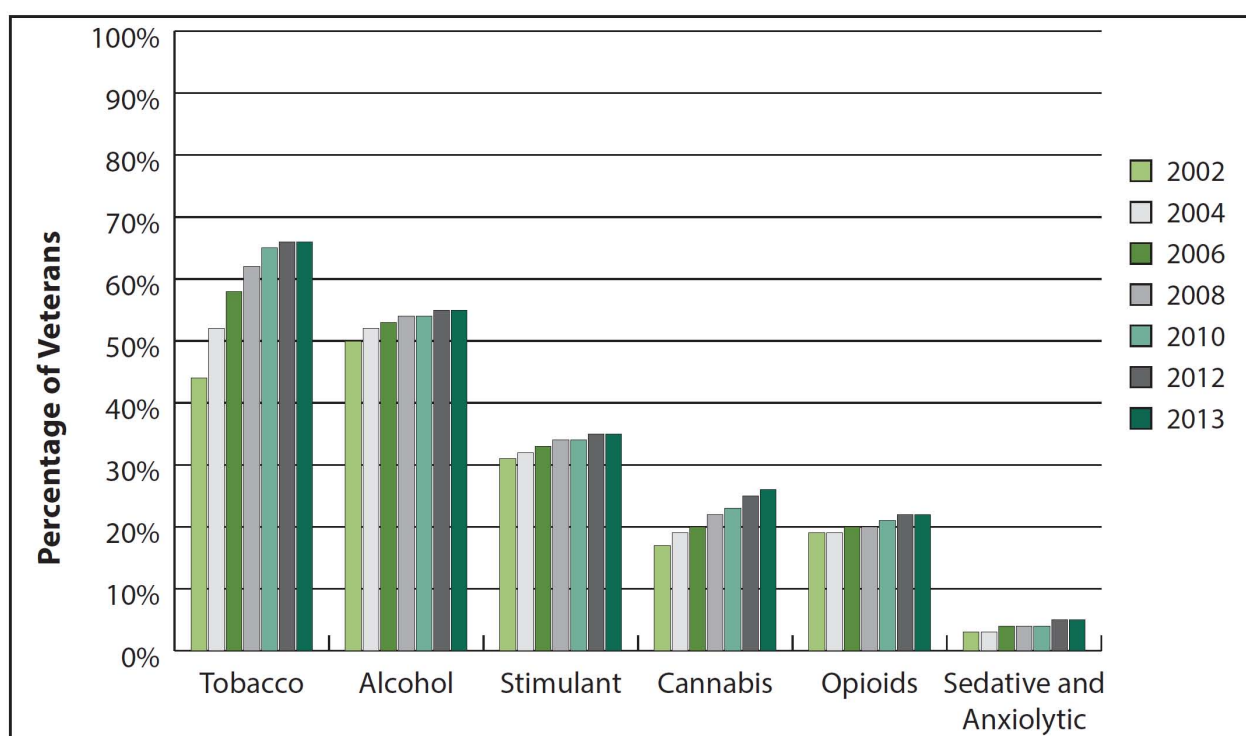


2.3.4 Comorbid substance use disorders

Between 2002 and 2013, alcohol use disorder remained the most common non-tobacco substance use disorder among Veterans with HCV, with 55% of HCV viremic Veterans in care in 2013 with a history of problematic alcohol use. In 2013, tobacco use was the most common substance used, with 66% of HCV viremic Veterans in care with a history of tobacco use. The percentage of HCV viremic Veterans in care who had ever had a diagnosis related to use of a specific substance increased for all substance categories between 2002 and 2013 (Figure 6).

Alcohol accelerates the progression of liver disease in those with HCV infection (Poynard, et al. 1997; Ostapowicz, et al. 1998); therefore, the large number of HCV viremic Veterans with a history of problematic alcohol use is of significant clinical and policy importance. As with the effort to promote screening for mental health conditions in the past decade, there has been a parallel effort to promote the diagnosis of substance use disorders. This effort likely accounts for some of the observed increase. In addition, these results reflect Veterans who had ever received a diagnosis of substance use, but do not reflect the proportion of those Veterans who no longer have an active substance use disorder.

Figure 6. Proportion of HCV viremic Veterans in care with tobacco, alcohol, stimulant, cannabis, opioid, and sedative and anxiolytic use diagnoses: 2002-2013



2.3.5 Comorbid general medical conditions

Veterans with HCV infection often have additional medical diagnoses that impact their health, increase the complexity of their care, may limit their ability to access care, or make antiviral therapy more challenging or toxic (in the case of an absolute contraindication to an antiviral medication). In addition to the high prevalence of mental health and substance use disorders outlined above, Table 3 shows that more than 20% of HCV viremic Veterans in care in 2013 had ever received a diagnosis of the following conditions: hypertension (69%), dyslipidemia (43%), esophageal disease (36%), diabetes (33%), anemia (25%), and/or chronic obstructive pulmonary disease (23%).

Table 3. Comorbid medical conditions: 2002 and 2013

Comorbid Condition Group	Comorbid Condition	Number with Ever Diagnosis of Condition		Percent* with Ever Diagnosis of Condition	
		2002	2013	2002	2013
Cardiovascular	Cardiomyopathy	1,964	5,133	1%	3%
	Cerebral Vascular Conditions	1,912	8,186	1%	5%
	Conduction Disorders / Dysrhythmias	10,470	23,883	7%	14%
	Congestive Heart Failure	4,917	11,444	3%	7%
	Hypertension	71,545	120,685	49%	69%
	Ischemic Heart Disease	18,099	29,790	12%	17%
	Pancreatic Disease	4,973	8,529	3%	5%
Hematologic	Anemia	17,777	43,215	12%	25%
Metabolic	Diabetes, Type I	9,353	7,448	6%	4%
	Diabetes, Type II and Unspecified	26,921	50,131	18%	29%
	Dyslipidemia	26,674	75,127	18%	43%
Pulmonary	Asthma	7,599	12,428	5%	7%
	COPD	19,144	40,333	13%	23%
	Emphysema	2,898	4,901	2%	3%
Renal	Renal Failure, Acute	2,775	17,446	2%	10%
	Renal Failure, Chronic	4,395	15,557	3%	9%

* Number of HCV viremic Veterans in care in year used as denominator: 146,290 (2002); 174,302 (2013)

2.4 Deaths

Among the 161,520 HCV viremic Veterans who were in VHA care in 2002 or in the preceding year, 1.8% (2,832) died in 2002. (Deaths among those Veterans in VHA care in the preceding year are included, since some Veterans may have VHA as their care provider until they are enrolled in home hospice, after which they do not subsequently utilize VHA services.) Among the 188,585 HCV viremic Veterans who were in VHA care in 2013 or the preceding year, 4.1% (7,812) died in 2013, representing a relative increase of 128% in the annual all-cause mortality rate over 2002. The available data do not allow determination of what proportion of these deaths were due to liver-specific causes.

2.5 Health care services provided to Veterans with HCV infection

Of the 174,302 HCV viremic Veterans in care in 2013, 71,558 had at least one visit in a gastroenterology, hepatology, or infectious diseases clinic, amassing a total of 230,849 visits to these three types of clinics. That same year, 3,494 HCV viremic Veterans in care had at least one clinic visit with palliative care or hospice; 35,306 HCV viremic Veterans had at least one inpatient admission, accruing a total of 73,297 inpatient admissions. Almost all HCV viremic Veterans in care had an outpatient prescription filled in 2013 (164,473 Veterans), for a total of 7,138,839 outpatient prescription fills in that year.

Chapter 3: Antiviral therapy for hepatitis C virus infection

From 2001 to 2011, standard treatment for HCV consisted of pegylated interferon and ribavirin. Treatment was prolonged (48 weeks for patients with genotype 1 infection), accompanied by many serious side effects, and yielded relatively low cure rates.¹⁰ In 2011, FDA approved the first generation of direct-acting antiviral agents (DAAs), boceprevir and telaprevir, to be used in conjunction with pegylated interferon and ribavirin for the treatment of genotype 1 HCV infection. These new regimens offered higher cure rates, but did not eliminate the need for pegylated interferon and ribavirin and their associated toxicities, and did not reduce the duration of therapy.

In late 2013, FDA approved two second-generation DAAs, simeprevir and sofosbuvir. Simeprevir, an NS3/4A HCV protease inhibitor, was approved for treatment of HCV genotype-1-infected patients, as part of a treatment regimen including pegylated interferon and ribavirin. Sofosbuvir, an NS5B HCV polymerase inhibitor, was approved for the treatment of infection due to HCV genotypes 1, 2, 3, or 4 in patients with HCV monoinfection and patients with HIV/HCV coinfection. Sofosbuvir, in conjunction with pegylated interferon and ribavirin, was approved for treatment of infection due to HCV genotypes 1 or 4. Sofosbuvir and ribavirin dual therapy was approved as an all-oral regimen for treatment of infection due to HCV genotypes 2 or 3. The second-generation DAAs made possible shorter durations of therapy, as well as a substantial increase in cure rates over the first-generation DAAs.

This advance in treatment options will continue, with interferon-free therapies expected to be available for most HCV-infected patients by 2015. These new therapies will make antiviral therapy a realistic option for many patients whose comorbid mental health and medical conditions preclude the use of interferon. VHA is rapidly and proactively incorporating these new medications into its national formulary, assessing the clinical and financial resources necessary to capitalize on these advances, and scaling up the infrastructure necessary to expand HCV therapy.

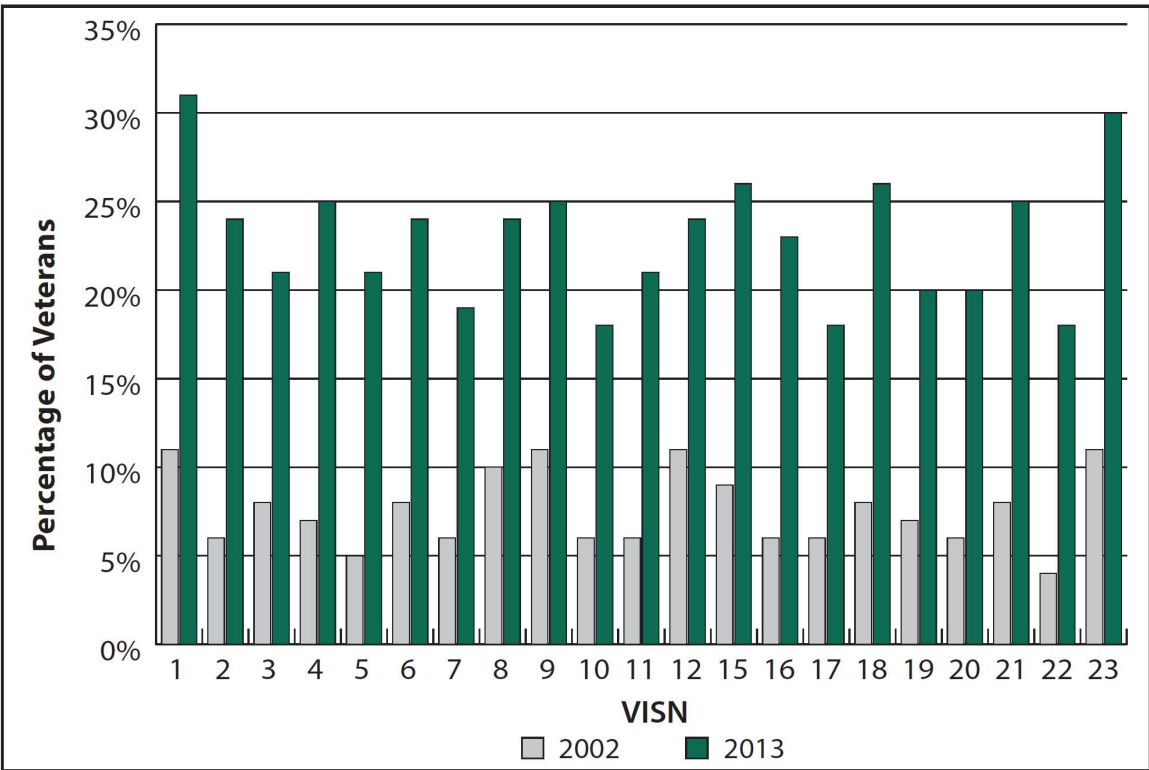
3.1 Receipt of antiviral therapy

Of the 174,302 HCV viremic Veterans in care (including all genotypes) in 2013, 23% (39,388) had ever filled a VHA outpatient prescription for any HCV antiviral medication. This ranged from 18% in VISNs 10, 17, and 22, to 31% in VISN 1 (Figure 7). Estimates of receipt of treatment in non-Veteran U.S. populations are limited; recent studies have yielded a broad range of treatment estimates, with estimates as of 2006 ranging from 10% to 19% (Kanwal, et al. 2010; North, et al. 2013).

Use of pegylated interferon and ribavirin in both Veteran and non-Veteran populations has been limited by the long duration of therapy (up to 48 weeks), the many adverse effects, and the many clinical and biochemical parameters or conditions (including depression) that preclude treatment. This two-drug regimen also resulted in low sustained virologic response (SVR) rates of approximately 35% for genotype 1 HCV-infected Veterans in VHA care (Backus, et al. 2011).

¹⁰ "Cure" of HCV infection is defined as achieving sustained viral response (SVR). SVR is defined as absence of detectable HCV in the blood at a defined time point after anti-viral treatment, and is a surrogate endpoint for cure of HCV infection. SVR is associated with greatly decreased risks of progression of HCV infection to cirrhosis, liver failure, and HCC. SVR has traditionally been defined as clearance of viremia 24 weeks after the end of treatment; more recently, SVR at 12 weeks after end of therapy has been considered evidence of cure. Relapse is rare among those who have achieved an SVR.

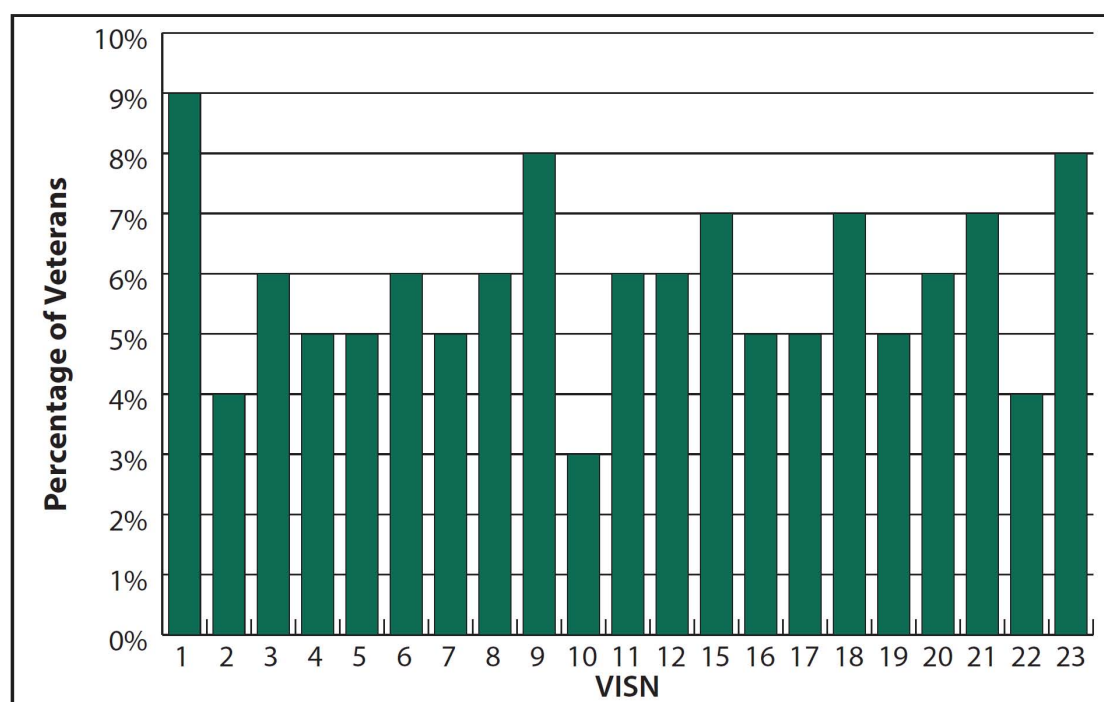
Figure 7. Percentage of HCV viremic Veterans in care who had *ever* filled a VHA outpatient prescription for any HCV antiviral medication prior to or during the target calendar year, by VISN: 2002 and 2013



3.2 Approval and clinical use of direct-acting antiviral agents

Of the 99,166 HCV viremic genotype 1 Veterans in care in 2013 without HIV coinfection, 5.8% (5,732) had *ever* received boceprevir or telaprevir. By VISN, the percentage ranged from 3% to 9% (Figure 8). Of the 99,166 HCV viremic genotype 1 Veterans in care in 2013 without HIV coinfection, 2% (1,796) *first* received boceprevir or telaprevir in 2013. By VISN, the percentage ranged from 1% to 2%. These treatment numbers are low, likely due to the complexity of this regimen and broad provider awareness of the impending approval of the second-generation agents.

Figure 8. Percentage of HCV viremic monoinfected genotype 1 Veterans in care who had ever received direct-acting antiviral medication, by VISN: 2013



3.3 Effectiveness of antiviral regimens containing telaprevir or boceprevir in the Veteran population

SVR rates among HCV-infected Veterans receiving triple therapy with pegylated interferon and ribavirin and either boceprevir or telaprevir are much improved over the prior pegylated interferon and ribavirin regimen. Among a cohort of Veterans identified from the CCR: HCV who had genotype 1 monoinfection and initiated triple therapy prior to January 2012, SVR was achieved in 50% of patients receiving boceprevir-based triple therapy and 52% of patients receiving telaprevir-based triple therapy (Backus, et al. 2014).¹¹ Not unexpectedly, the SVR rates in HCV-infected Veterans treated with triple therapy regimens were lower than rates reported in clinical trials, which by design enroll patients who are more likely to adhere to and complete therapy and to achieve an SVR, and less likely to have comorbidities or drug toxicities.

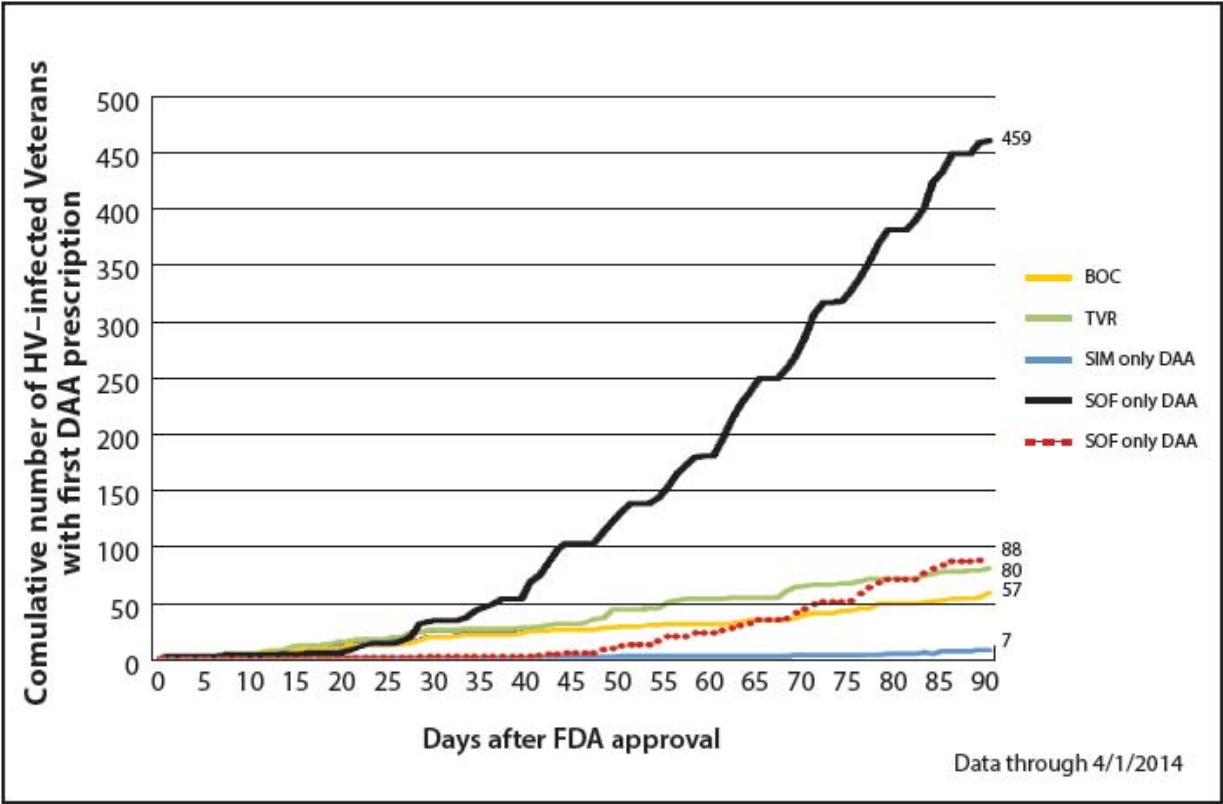
3.4 Uptake of new antiviral regimens containing simeprevir and sofosbuvir in the Veteran population

In the months since FDA's approval of sofosbuvir and simeprevir, VHA has been vigorously promoting appropriate use of these new agents with demonstrated rapid uptake. Within the first three months after the FDA approval, 459 Veterans had been started on sofosbuvir-based therapy (Figure 9). Uptake of sofosbuvir in VHA has been much faster than the initial uptake of boceprevir and telaprevir. Newer HCV antivirals under development are expected to be even more effective, less toxic, and easier to administer, giving providers a much wider selection of DAAs from which to choose, and permitting tailoring of safe, effective regimens to the needs of individual Veterans.

¹¹ The following groups were excluded from the analysis: those with a diagnosis of HCC or liver transplant, and those who had undetectable viral loads after the end of treatment but lacked HCV RNA testing at least 12 weeks after the end of treatment.

Figure 9. Cumulative number of Veterans started on DAAs in the first 90 days of VHA availability

BOC = boceprevir; TVR = telaprevir; SIM = simeprevir; SOF = sofosbuvir;
DAA = direct-acting antiviral medication



Chapter 4: Quality of care

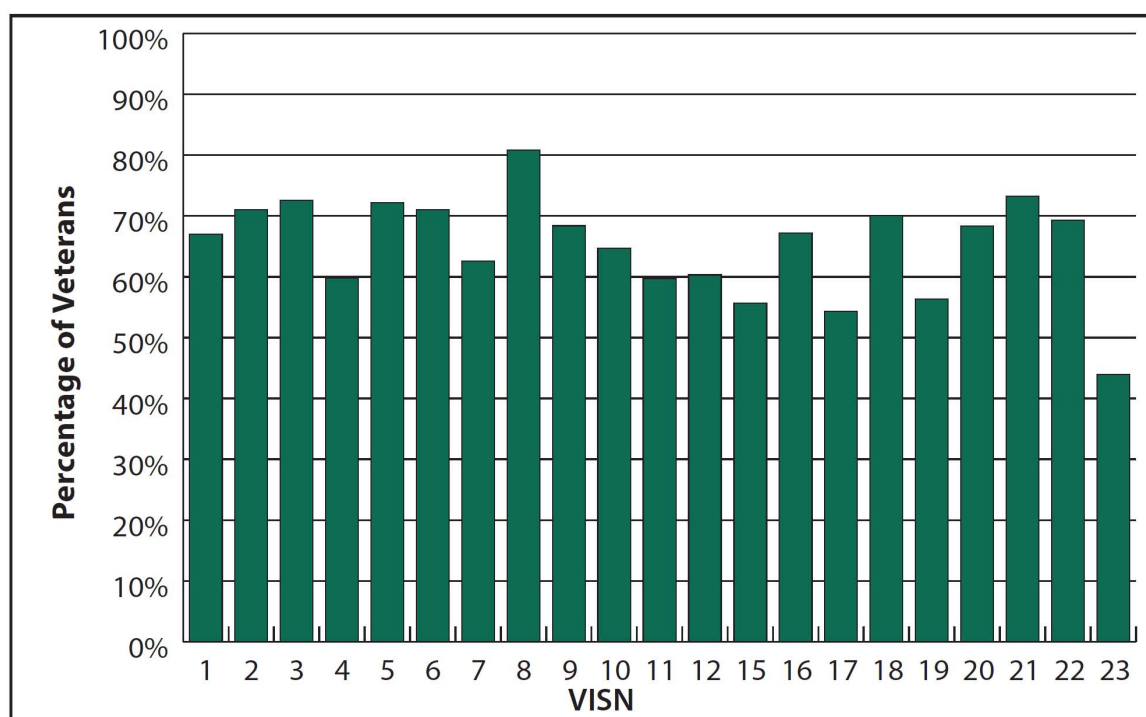
4.1 Hepatitis C virus screening

Prior to August 2012, all major national guidelines – from CDC, the United States Preventive Services Task Force (USPSTF), the American Association for the Study of Liver Diseases (AASLD), and VHA – recommended risk-based screening for HCV. In August 2012, CDC issued new guidelines recommending HCV screening for anyone born between 1945 and 1965. In June 2013, USPSTF also recommended one-time screening of all persons born between 1945 and 1965. In November 2013, the VHA Preventive Medicine Field Advisory Committee approved a new Clinical Preventive Services Guideline recommending HCV screening for the 1945-65 birth cohort; this guidance was released by VHA NCP in January 2014. These guidelines recommend one-time screening for all Veterans within this birth cohort, in addition to all Veterans who have known risk factors. For more information on this guidance see [http://vaww.prevention.va.gov/Screening for Hepatitis C.asp](http://vaww.prevention.va.gov/Screening%20for%20Hepatitis%20C.asp).

Between 2002 and 2013, the percentage of Veterans with at least one outpatient visit in the year who had ever received screening doubled from 26.9% to 56.0%. Sixty-five percent of Veterans born between 1945 and 1965 with at least one outpatient visit in 2013 had ever been screened for HCV.¹²

Figure 10 shows HCV screening among Veterans in the 1945-65 birth cohort by VISN. Screening rates for this birth cohort ranged from 44% in VISN 23 to 81% in VISN 8. Screening rates for the 1945-65 cohort by Station are available at <http://vaww.vha.vaco.portal.va.gov/sites/PublicHealth/pophealth/hcvbirthcohort/default.aspx>.

Figure 10. Percentage of Veterans in the 1945-65 birth cohort in care who had ever received VHA HCV screening, by VISN: 2013



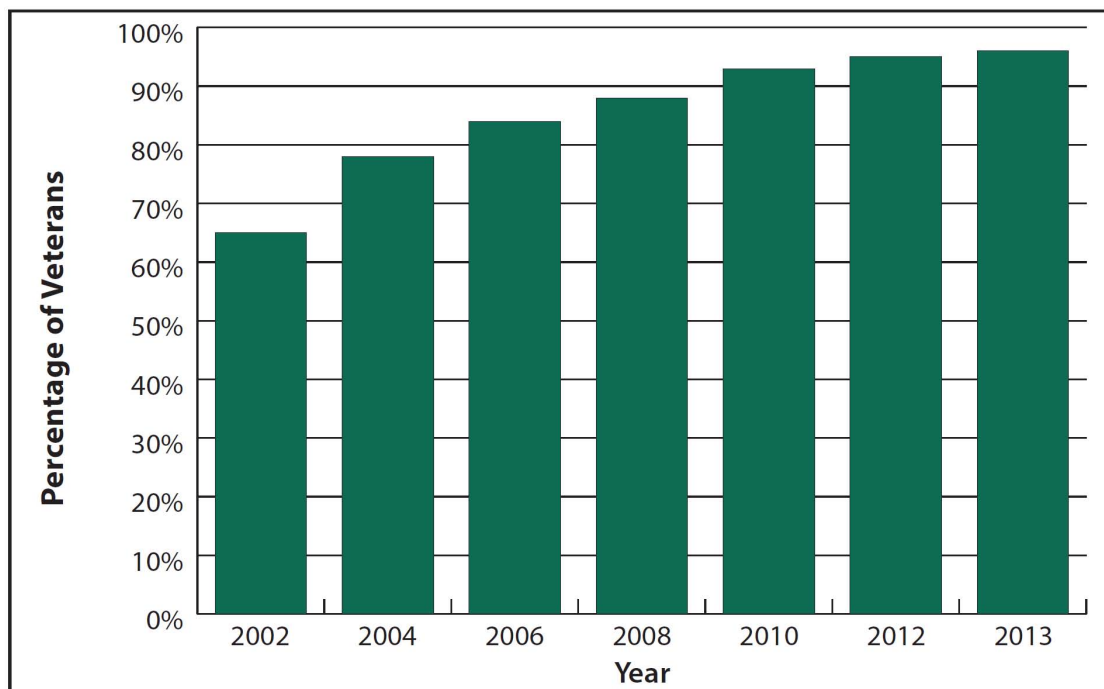
¹² Hepatitis C screening data were derived from the Corporate Data Warehouse.

4.2 Confirmatory testing

Because 15-25% of individuals infected with the HCV spontaneously clear the virus (Smith, et al. 2012), CDC recommends that a positive HCV screening antibody result be followed by confirmatory nucleic acid testing (Centers for Disease Control and Prevention 2013). Since 2009, VHA has required reflex confirmatory nucleic acid testing (i.e., automatic testing without the need for a second blood draw) following a positive HCV screening antibody result, in order to identify patients with ongoing HCV infection, facilitate linkage to care, and evaluate for potential antiviral treatment.

Between 2002 and 2013, the percentage of Veterans with positive screening antibody results for HCV who also received confirmatory testing with either genotype or viral load testing increased from 65% to 96% (Figure 11). This marked increase was due to a successful nationwide quality improvement effort conducted by OPH involving a policy change mandating reflex confirmatory testing at VA Medical Centers; construction and dissemination of a standardized confirmatory testing algorithm for all VHA medical facilities; detailed audit and feedback reports to individual VA Medical Centers; and transitional funding support for laboratory implementation of confirmatory testing.

Figure 11. Percentage of Veterans in care with positive HCV screening antibody results who had ever received confirmatory testing: 2002-13



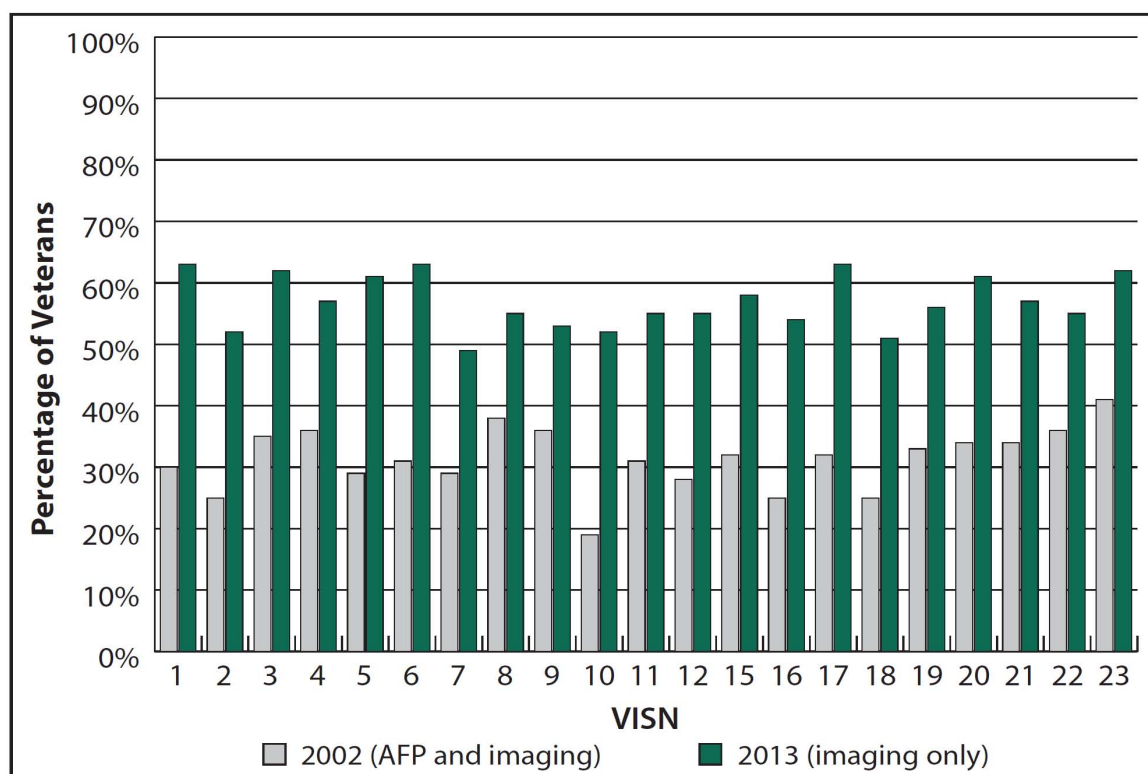
4.3 HCC surveillance

Currently, AASLD recommends surveillance of patients at high risk for development of HCC¹³ with hepatic imaging (ultrasound, computerized tomography, or magnetic resonance imaging) every six months (Bruix, Sherman 2011). Prior to 2010, AASLD had recommended HCC surveillance by performing hepatic imaging and measuring serum alpha-fetoprotein (AFP) concentrations every six months.

¹³ AASLD defines patients at high risk for development of HCC as individuals with chronic HCV infection who have developed cirrhosis, various categories of individuals with chronic hepatitis B virus infection, and patients with some forms of autoimmune cirrhosis.

In 2002, of the 9,558 HCV viremic Veterans in care with a diagnosis of cirrhosis prior to 2002, 30% received surveillance with AFP and hepatic imaging, 11% received AFP surveillance only, and 14% received hepatic imaging only in that year. In 2013, among 25,324 HCV viremic Veterans in care with a diagnosis of cirrhosis prior to 2013, 56% received hepatic imaging (the updated standard of care for HCC surveillance) (Figure 12). Although effective screening showed an absolute increase of 20% in a number of VISNs over the time period, there is much room for improvement in HCC surveillance nationally across the VHA system.

Figure 12. Percentage of HCV viremic Veterans with known cirrhosis in care who received recommended HCC screening (AFP and imaging in 2002 and imaging only in 2013), by VISN: 2002 and 2013



4.4 Influenza immunization

The CDC Advisory Committee on Immunization Practices (ACIP) recommends annual influenza vaccination for individuals with HCV infection. During the 2012/2013 influenza season, 163,612 HCV viremic Veterans in VHA care were eligible for the influenza vaccine (i.e., no vaccine allergy), and 59% of those received the vaccine, compared with 39% in 2002 (Figure 13). These proportions are likely an underestimate because of the number of Veterans who receive influenza vaccination outside the VHA system as well as variations in how administration of influenza vaccination is documented in VHA's EHR. Influenza vaccination rates among HCV-infected Veterans in VHA care in 2013 ranged from 54% in VISN 10 to 65% in VISNs 4 and 17 (Figure 14). Despite the absolute 20% increase nationally in influenza vaccination rates in HCV-infected Veterans in VHA care between 2002 and 2013, significant room for improvement remains.

Figure 13. Percentage of eligible HCV viremic Veterans in care who received the influenza vaccine: 2002-13

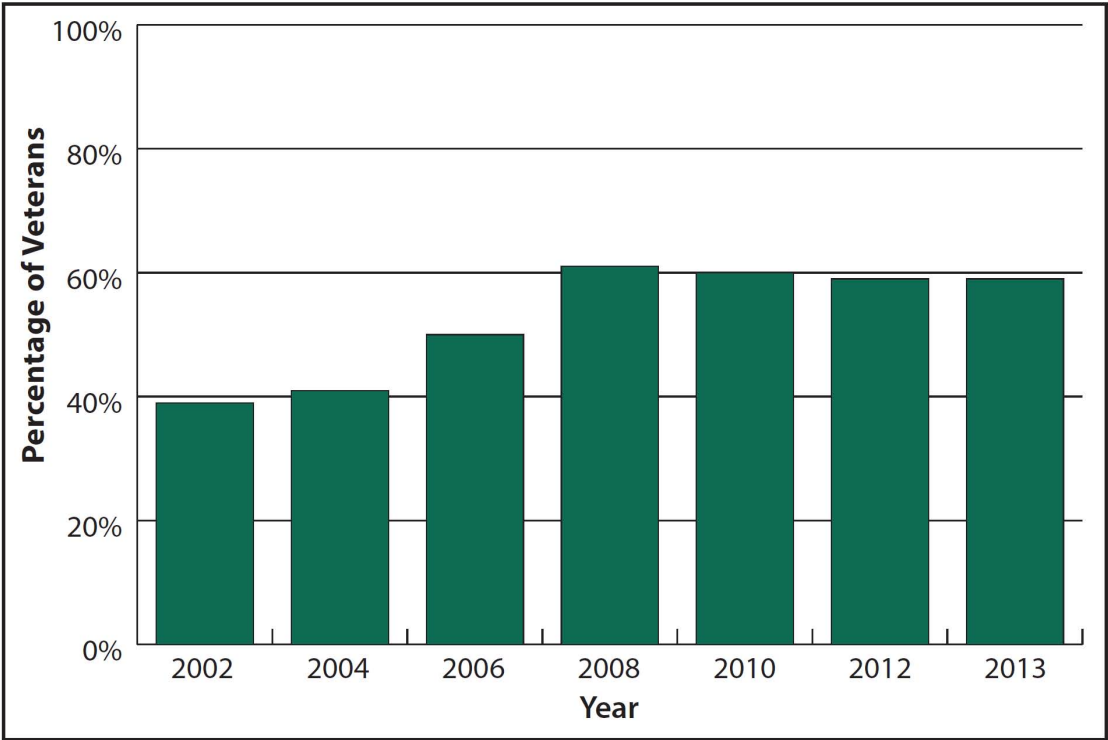
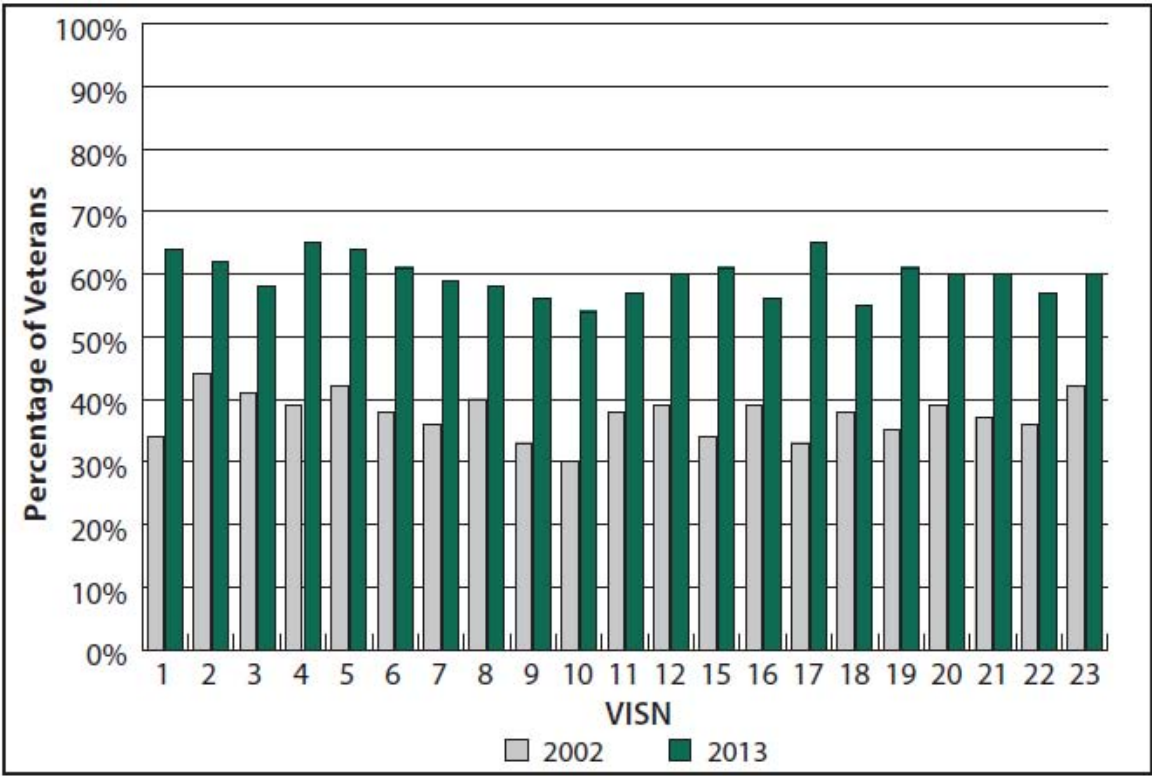


Figure 14. Percentage of eligible HCV viremic Veterans in care who received the influenza vaccine, by VISN: 2002 and 2013



4.5 Hepatitis A virus immunization

The CDC ACIP recommends that all patients with chronic liver disease without immunity to hepatitis A virus receive the hepatitis A virus vaccine.

In 2002, 40% of HCV viremic Veterans had ever been tested for immunity to hepatitis A virus. Of those who were non-immune, 39% had received hepatitis A virus immunization. In 2013, 77% of HCV viremic Veterans had ever been tested for immunity to hepatitis A. Of those who were non-immune, 62% had received hepatitis A immunization (Figure 15). This represents an increase both in the percentage tested for immunity and in the percentage of non-immune HCV viremic Veterans who were immunized compared with the figures for 2002. Hepatitis A immunization of non-immune individuals ranged from a low of 50-51% in VISNs 3, 7, and 16, to a high of 79% in VISNs 1 and 21 in 2013 (Figure 16). Overall, 32% of HCV viremic Veterans in care in 2002 were either immune to or vaccinated against hepatitis A virus, increasing to 72% of HCV viremic Veterans in care in 2013.

Figure 15. Percentage of non-immune HCV viremic Veterans in care who had received hepatitis A virus immunization: 2002-13

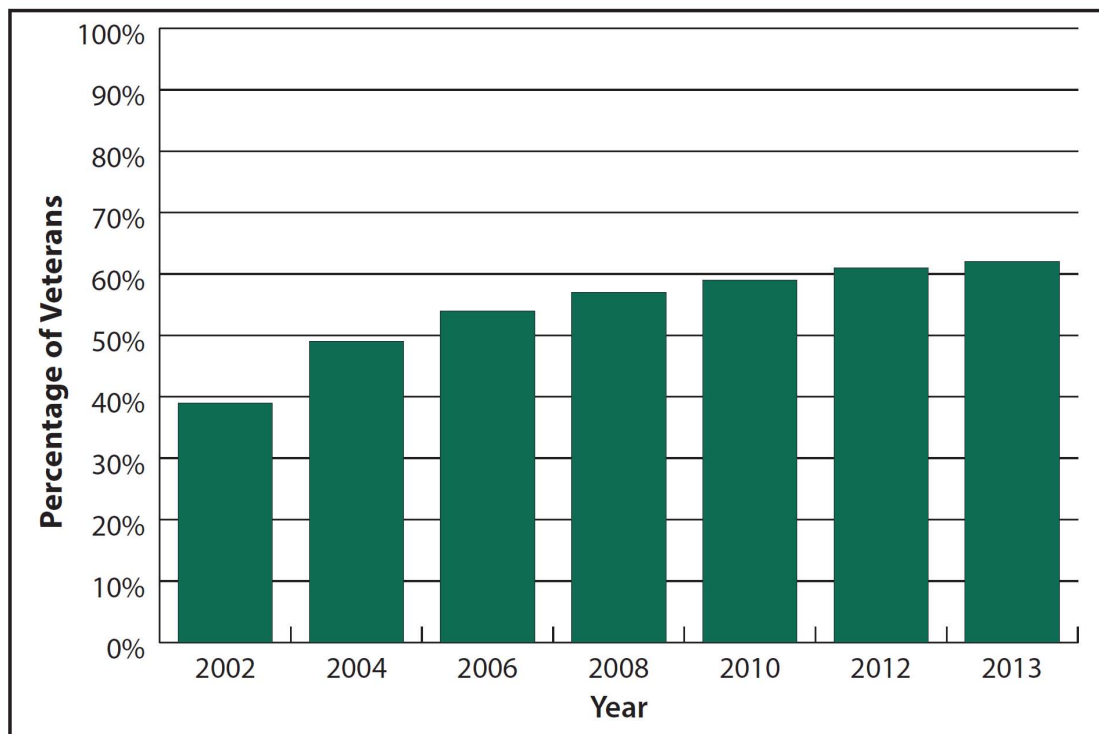
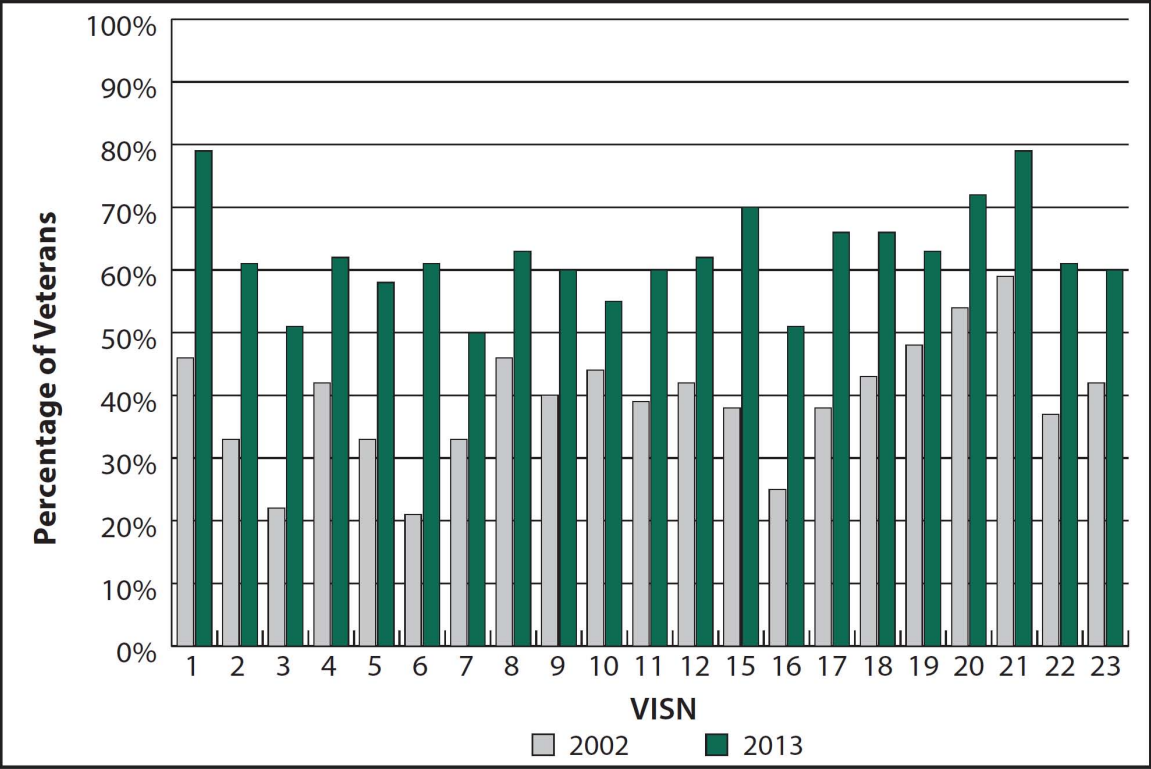


Figure 16. Percentage of non-immune HCV viremic Veterans in care who received hepatitis A virus immunization, by VISN: 2002 and 2013



4.6 Hepatitis B virus immunization

The CDC ACIP recommends that patients with chronic liver disease and without hepatitis B virus immunity receive the hepatitis B virus vaccine. In 2002, of 146,290 HCV viremic Veterans in care, 66% (96,633) had ever been tested for immunity to hepatitis B virus. Of the 44,369 HCV viremic Veterans found to be non-immune, 36% had ever received the hepatitis B virus vaccine. In 2013, of 174,302 HCV viremic Veterans in care, 90% (157,304) had ever been tested for immunity to hepatitis B virus. Of the 65,389 HCV viremic Veterans found to be non-immune, 64% had ever received the hepatitis B virus vaccine (Figure 17). This represents a marked increase in the absolute number and percentage of Veterans with HCV viremia who had ever been tested for hepatitis B virus immunity, as well as a near doubling of the percentage of non-immune HCV viremic Veterans who were immunized. The percentage of non-immune HCV viremic Veterans who had ever received hepatitis B vaccine ranged from 52% in VISN 7 to 80% in VISN 21 (Figure 18). Overall, excluding Veterans who were coinfectd with hepatitis B virus, 47% of HCV viremic Veterans in care in 2002 were either immune to or vaccinated against hepatitis B virus, which increased to 78% of HCV viremic Veterans in care in 2013.

Figure 17. Percentage of non-immune HCV viremic Veterans in care who had ever received hepatitis B virus immunization: 2002-13

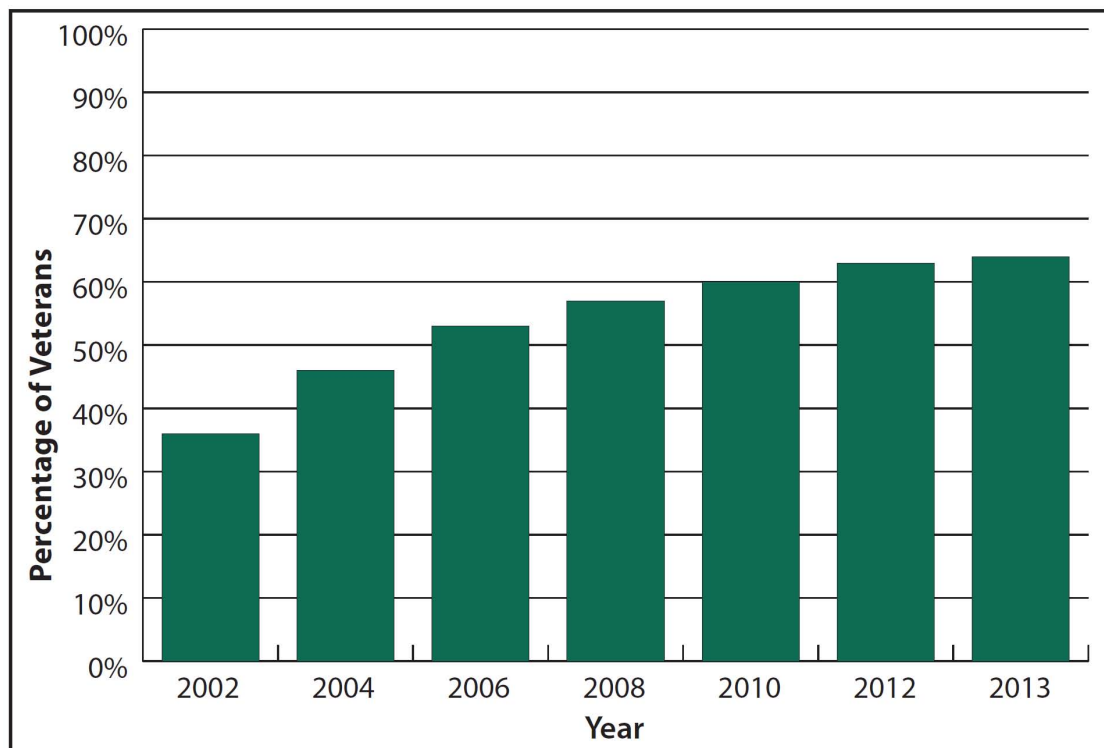
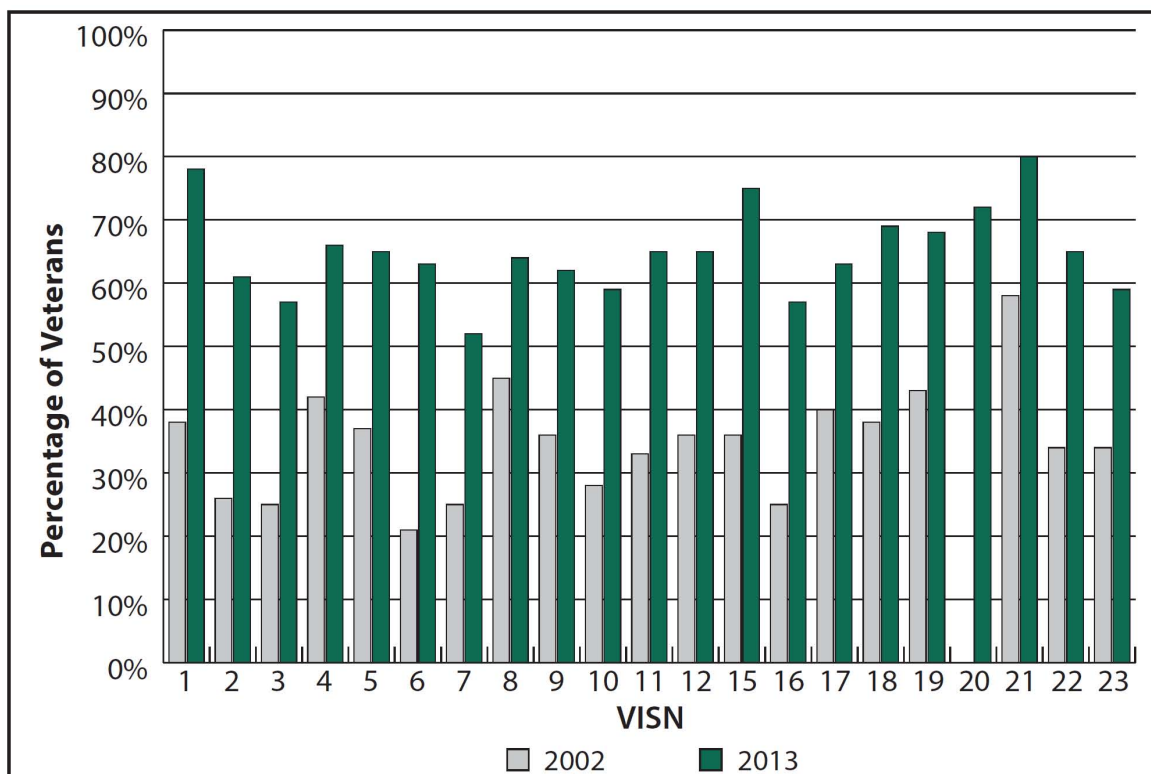


Figure 18. Percentage of non-immune HCV viremic Veterans in care who had ever received hepatitis B virus immunization, by VISN: 2002 and 2013



4.7 HIV screening

All major national guidelines (CDC, AASLD, and VHA) recommend routine HIV screening for patients with HCV infection. In addition, CDC and VHA recommend at least one-time HIV screening for all adults. In 2009, VHA changed its HIV screening policy and eliminated requirements for written informed consent and scripted pretest and posttest counseling. VHA now requires only documentation of verbal consent and the provision of written education materials on HIV testing. Between 2002 and 2013, the percentage of HCV viremic Veterans in care who had ever received HIV screening almost doubled from 39% to 76% (Figure 19). However, in 2013, rates of HIV screening among HCV viremic Veterans varied by more than 20% among different VISNs, ranging from 65% in VISN 23 to 86% in VISN 5 (Figure 20).

Figure 19. Rates of HIV screening among HCV viremic Veterans in care: 2002-13

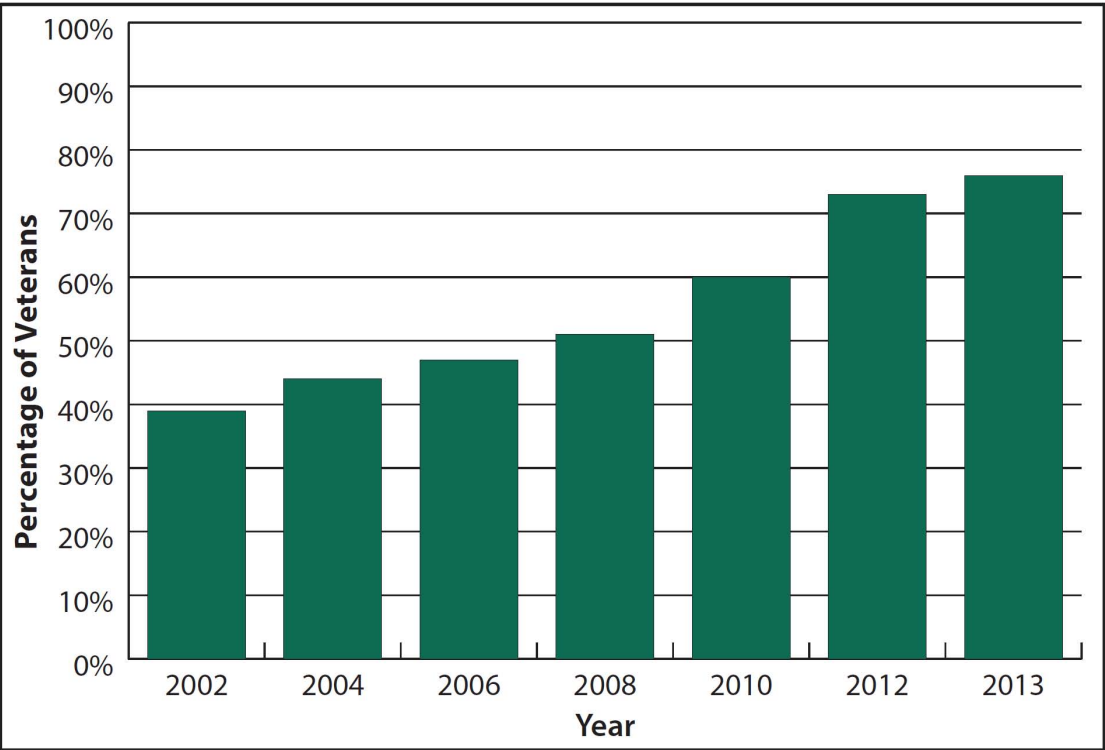
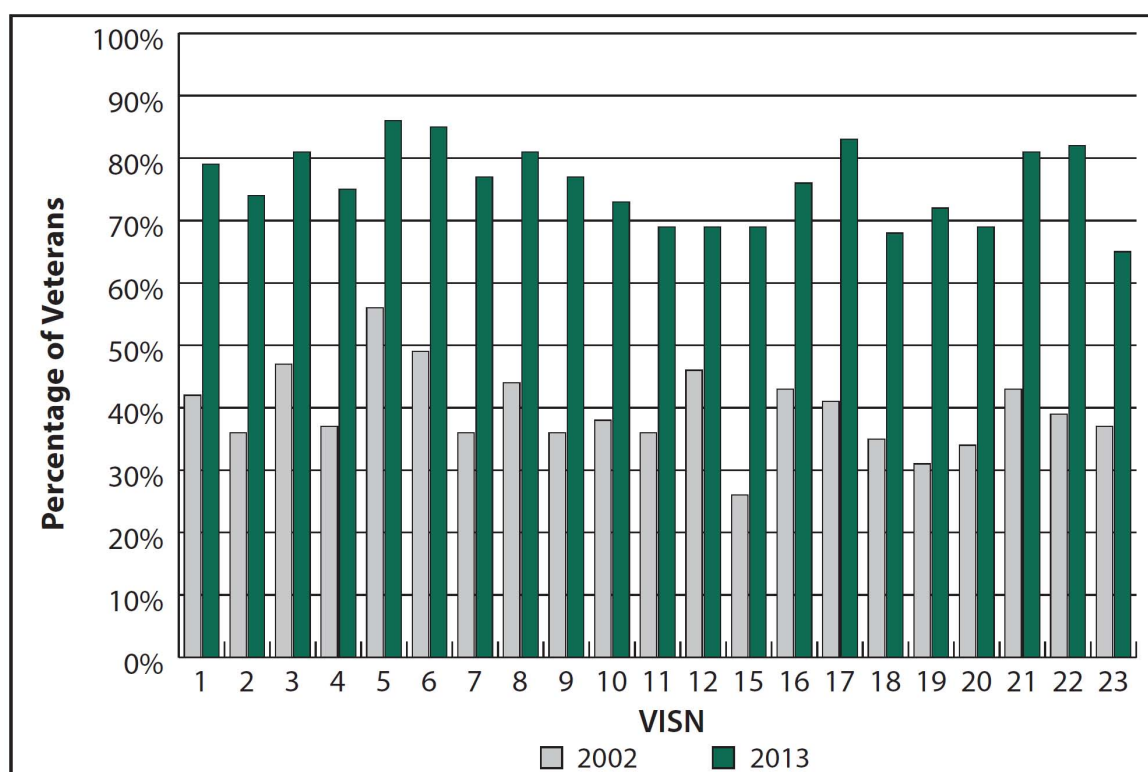


Figure 20. Rates of HIV screening among HCV viremic Veterans in care, by VISN: 2002 and 2013



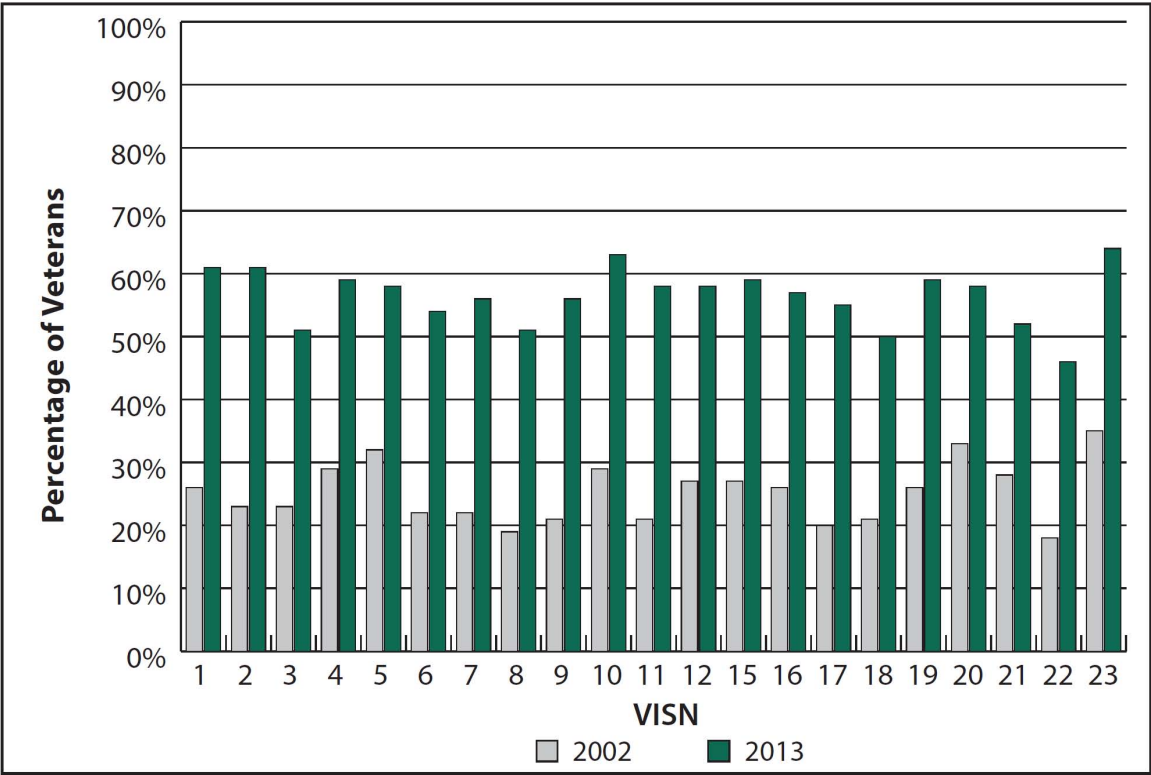
4.8 Tobacco use diagnosis and tobacco cessation

The 2008 update of the Public Health Services Clinical Practice Guideline on treating tobacco use and dependence concludes that health care delivery systems must identify tobacco use and treat every tobacco user (Fiore, et al. 2008).

In 2002, 44% of HCV viremic Veterans in care had ever had a diagnosis of tobacco use. Twenty-four percent of HCV viremic Veterans in VHA care in 2002 had ever filled an outpatient VHA prescription for smoking cessation pharmacotherapy, while 10% had filled an outpatient VHA prescription for pharmacotherapy for smoking cessation in 2002.

In 2013, 66% of HCV viremic Veterans in care had ever had a diagnosis of tobacco use (an absolute increase of 22% between 2002-2013). Fifty-five percent of HCV viremic Veterans in VHA care in 2013 had ever filled an outpatient VHA prescription for smoking cessation pharmacotherapy, while 20% had filled an outpatient VHA prescription for pharmacotherapy for smoking cessation in 2013 (twice the percentage of Veterans who had received a prescription for smoking cessation pharmacotherapy in 2002). The percentage of HCV viremic Veterans who had ever received a prescription for tobacco cessation ranged from 46% in VISN 22 to 64% in VISN 23 (Figure 21).

Figure 21. Percentage of HCV viremic veterans in care with a diagnosis of tobacco use ever who had ever received a prescription for tobacco cessation pharmacotherapy: 2002 and 2013

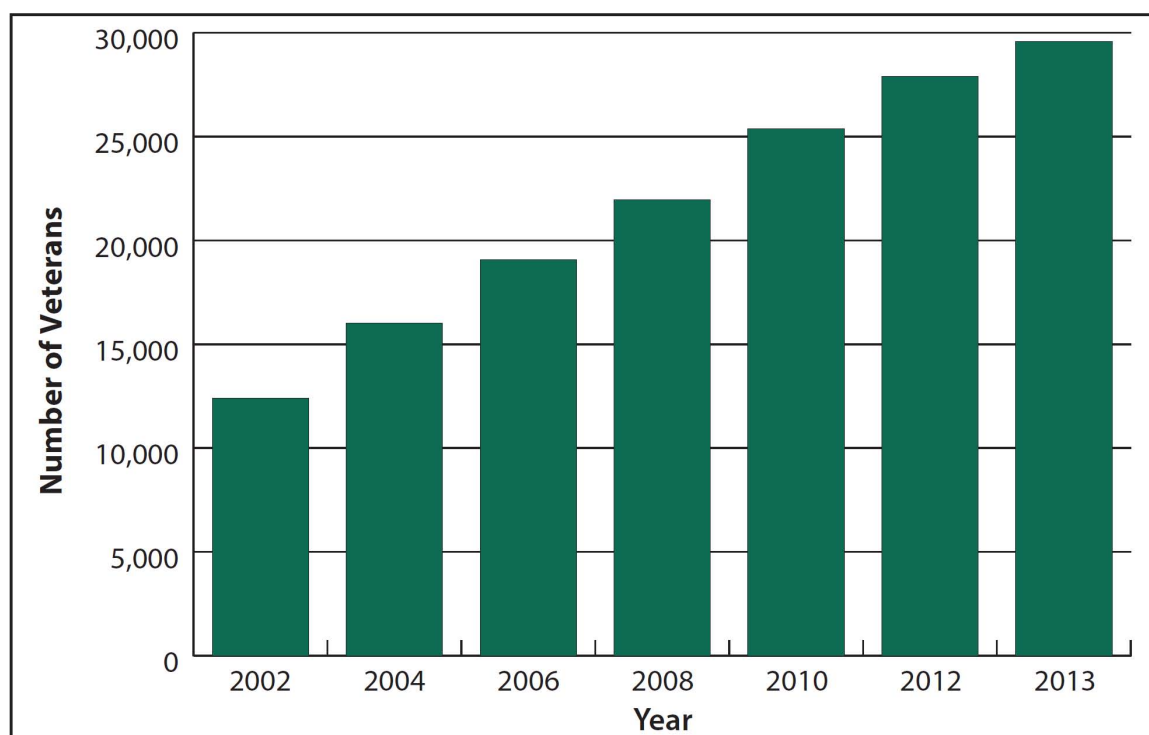


Chapter 5: Cirrhosis care

5.1 Cirrhosis demographics

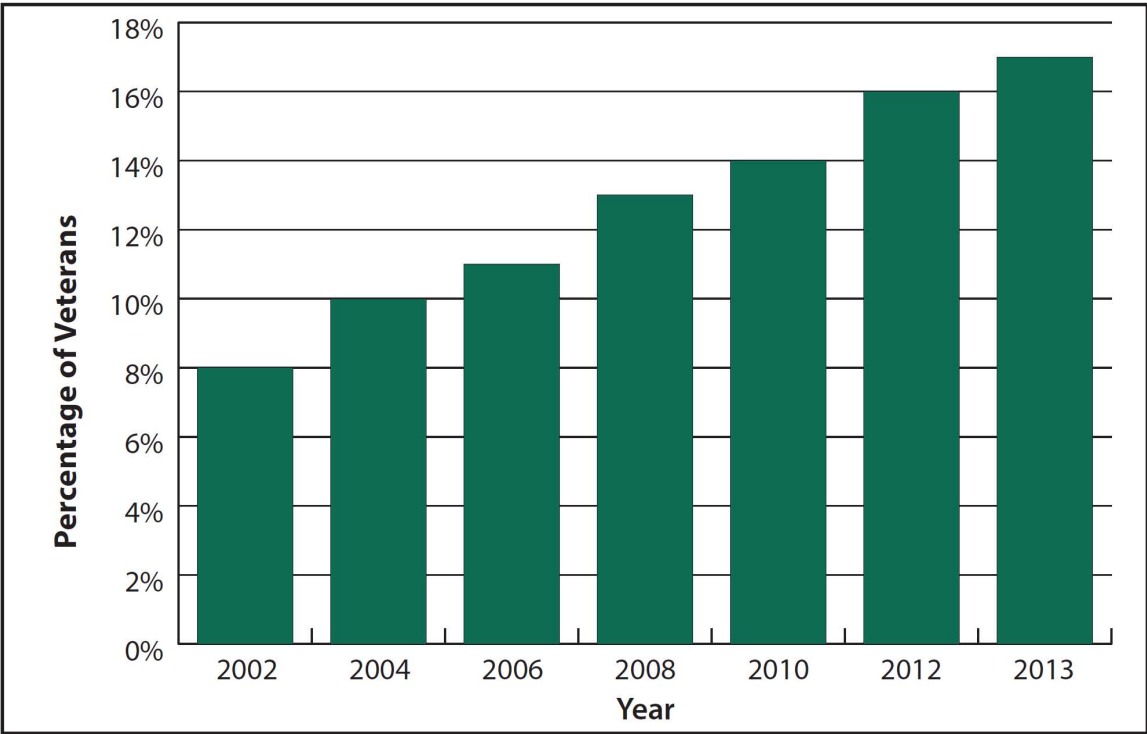
Among individuals with HCV infection, 10-20% will develop cirrhosis (Centers for Disease Control and Prevention 1998). Cirrhosis,¹⁴ and its sequelae of decompensated liver disease and HCC, are the most important clinical complications of HCV infection. The percentage of HCV viremic Veterans in care with new diagnoses of cirrhosis each year remained stable at 2-3% per year between 2002 and 2013, but due to the large numbers of Veterans with HCV infection, disease progression, and the high prevalence of interacting comorbidities such as HIV infection and alcohol use disorders, the cumulative burden of HCV-related cirrhosis in VHA is high and steadily increasing. Between 2002 and 2013, the number of HCV viremic Veterans in care with cirrhosis increased 138%, from 12,404 Veterans to 29,578 Veterans, and the percentage of HCV viremic Veterans with cirrhosis doubled from 8% to 17% (Figure 22 and Figure 23).

Figure 22. Number of HCV viremic Veterans in care who have ever received a diagnosis of cirrhosis: 2002-13



¹⁴ In this report, cirrhosis is defined using relevant ICD-9 diagnostic codes. Further details about the ICD-9 diagnostic codes used by the LDD can be found at <http://vaww.hepatitis.va.gov/ald-index.asp>.

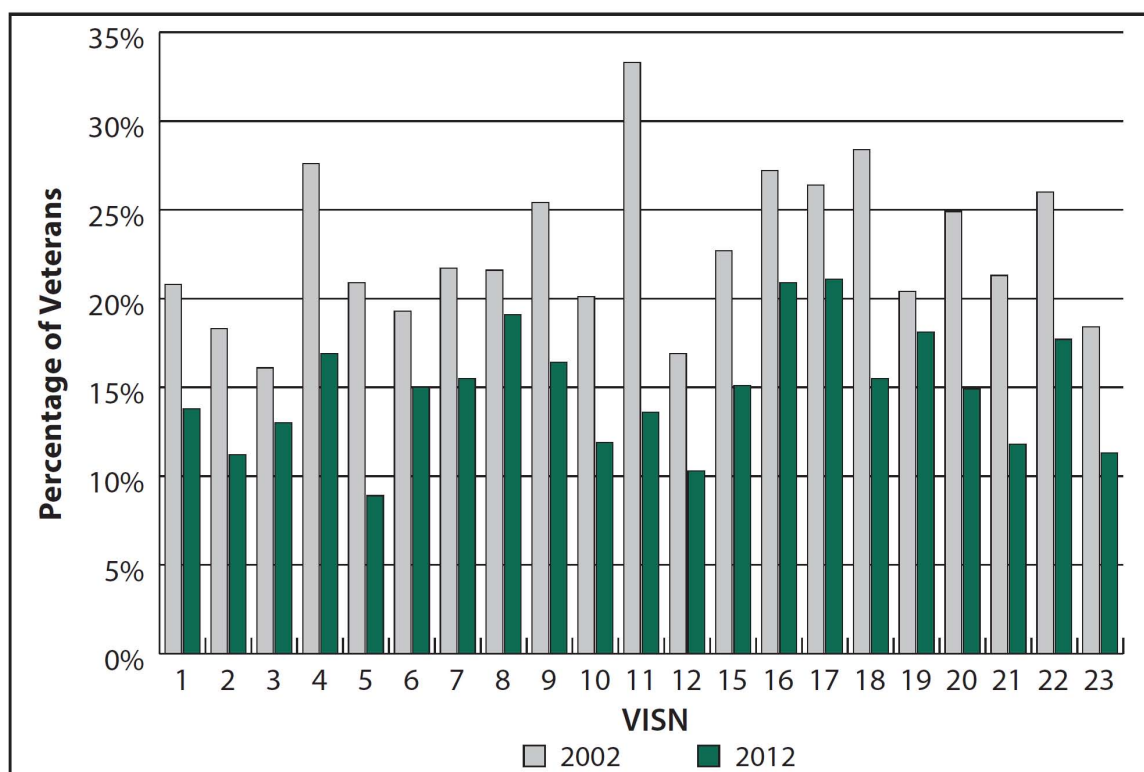
Figure 23. Percentage of HCV viremic Veterans in care who have ever been diagnosed with cirrhosis: 2002-13



Among Veterans with HCV infection in care, cirrhosis and HCV are important causes of hospital admissions in the last year of life. In 2002, among Veterans with HCV infection in care who died in calendar year 2002 and had at least one hospital admission at a VHA facility in the 12 months preceding death, 22% had a diagnosis of cirrhosis as the principal diagnosis upon discharge, while 3.2% had a primary diagnosis of HCV infection. In comparison, in 2012, among Veterans with HCV infection in care who died in calendar year 2012 and had at least one hospital admission at a VHA facility in the 12 months preceding death, 14% had a diagnosis of cirrhosis as the principal diagnosis upon discharge, while 4% had a primary diagnosis of HCV infection (Figure 24).¹⁵ The significance of this change is unclear. It may reflect an increase in the number of patients dying from end-stage liver disease diagnoses not captured under the term "cirrhosis" such as hepatic encephalopathy or variceal bleeds. Alternatively, it may represent an increasing incidence of competing mortality risks from non-liver causes in this aging population. Finally, the change may also simply reflect secular trends in diagnostic coding methodology.

¹⁵ Data on principal discharge diagnoses for hospital admissions in the last year of life among Veterans with HCV infection were obtained from the LDD.

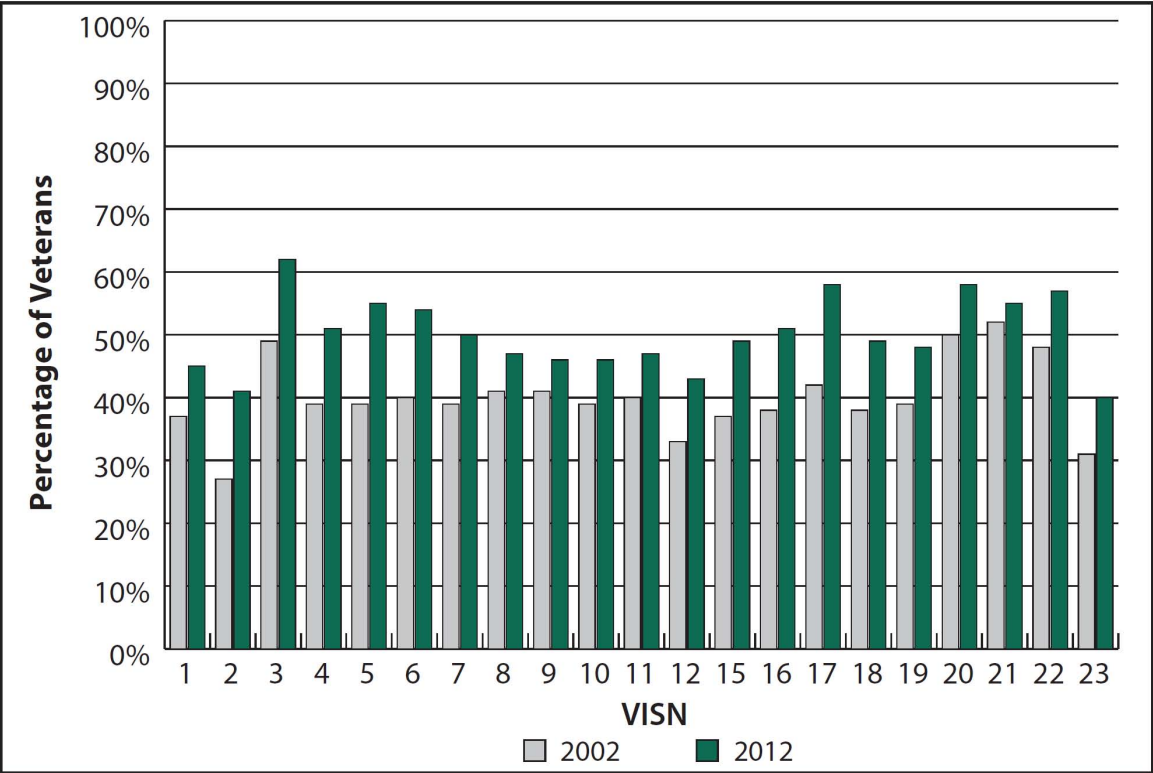
Figure 24. Prevalence of cirrhosis or HCV infection as primary discharge diagnoses among Veterans in care with HCV infection who died in the target calendar year and had one or more inpatient admissions at a VHA facility in the 12 months preceding death, by VISN: 2002-12



Nationally, among Veterans in care diagnosed with cirrhosis of any etiology, HCV is a substantive and increasing cause of cirrhosis. Of the 30,205 Veterans with cirrhosis in care in 2002, 11,751 (39%) had HCV infection.¹⁶ This increased to 32,349 Veterans, or 50% of the 64,845 Veterans with cirrhosis, in 2012. The prevalence of HCV infection among cirrhotic Veterans ranged from 40% in VISN 23 to 62% in VISN 3 (Figure 25). The large numbers of Veterans with cirrhosis combined with the increasingly important role HCV infection plays in causing cirrhosis among Veterans highlights the importance of rapid expansion of HCV antiviral therapy in this population.

¹⁶ The prevalence of HCV infection among cirrhotic Veterans nationally was determined using ICD-9 codes in data from the LDD.

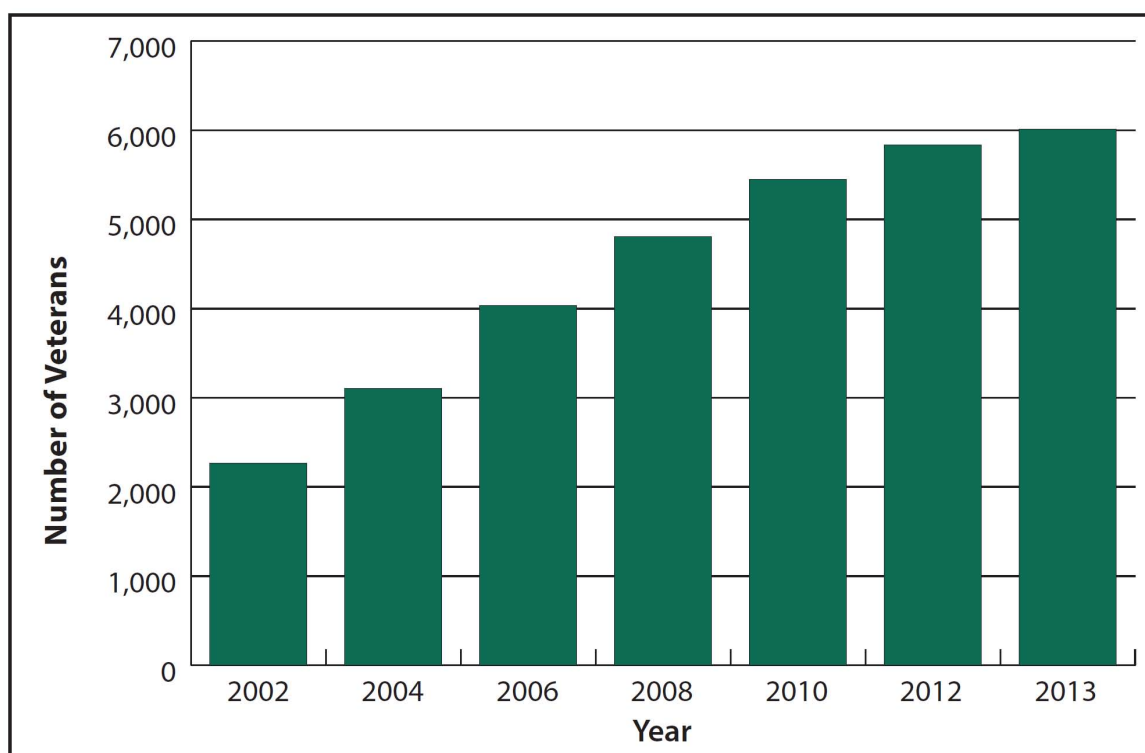
Figure 25. Prevalence of HCV infection among cirrhotic Veterans (all etiologies) in care, by VISN: 2002-12



5.2 Decompensated liver disease

Parallel with the increase in cirrhosis among HCV viremic Veterans, the incidence of new diagnoses of decompensated liver disease (a sequela of cirrhosis associated with a poor prognosis and decreased lifespan) increased from 0.6% (831) of 146,290 HCV viremic Veterans in care in 2002 to 0.9% (1,598) of 174,302 HCV viremic Veterans in care in 2013. The number of HCV viremic Veterans who had ever been diagnosed with decompensated liver disease prior to or during the target calendar year increased from 1.5% (2,267) of HCV viremic Veterans in care in 2002 to 3.4% (6,013) of HCV viremic Veterans in care in 2013 (Figure 26). The clinical complications that define decompensated liver disease (i.e., variceal hemorrhage, ascites, spontaneous bacterial peritonitis, and hepatic encephalopathy) negatively affect a patient’s quality of life, and contribute to the high cost of care for individuals with cirrhosis.

Figure 26. Number of HCV viremic Veterans in care who had ever been diagnosed with decompensated liver disease prior to or during the target calendar year: 2002-13



5.3 Hepatocellular carcinoma

Although the absolute number of HCV viremic veterans in care with a *new* diagnosis of HCC in 2002 was small (274 patients), there was a six-fold increase in the number of patients with a new diagnosis of HCC between 2002 and 2013, with 1,654 new diagnoses in 2013 (Figure 27). Between 2002 and 2013, there was a more than nine-fold increase in the number of HCV viremic Veterans who had *ever* received a diagnosis of HCC prior to or during the target year, increasing from 516 Veterans to 4,916 Veterans (Figure 28). The difference between the number of first diagnoses in 2013 (1,654) and the change in the number of patients ever diagnosed with HCC between 2012 and 2013 (175) likely reflects the short survival of patients newly diagnosed with HCC. This trend is expected to continue, as most cases of HCC develop in the setting of cirrhosis, and the number of Veterans with cirrhosis is projected to increase. If detected at an early stage, HCC is curable by liver transplantation, tumor resection, or tumor ablation.

Figure 27. Number of HCV viremic Veterans in care with first diagnosis of hepatocellular carcinoma: 2002-13

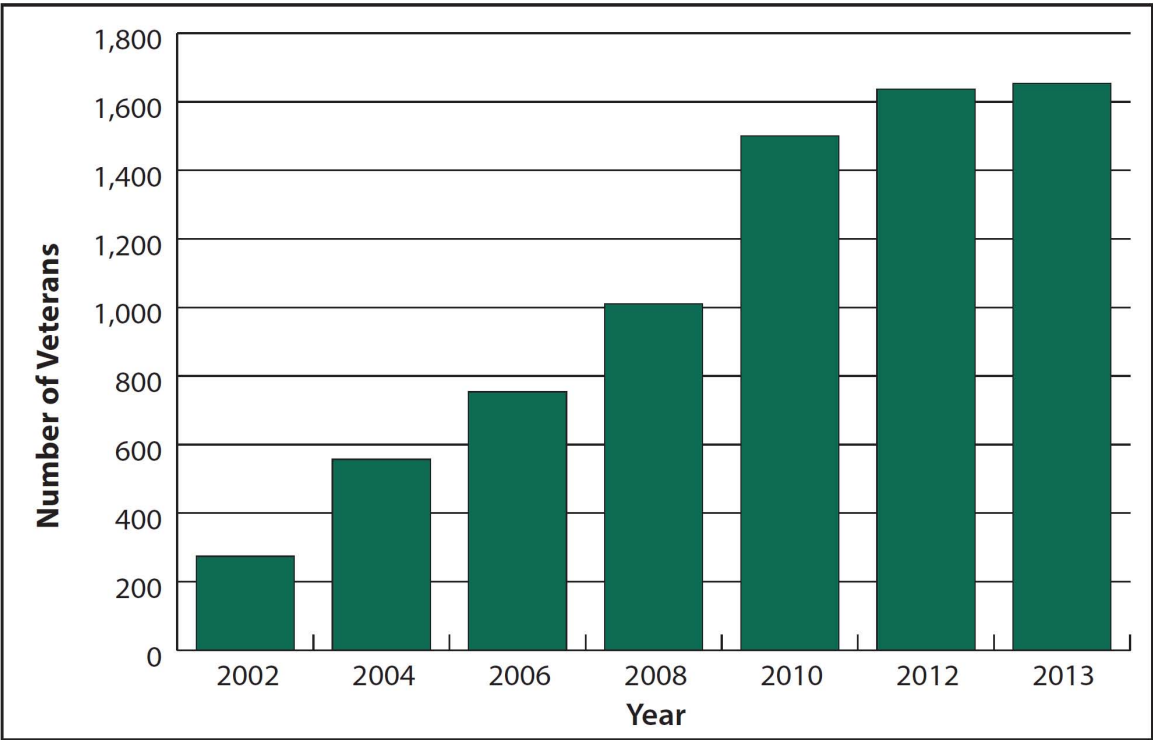
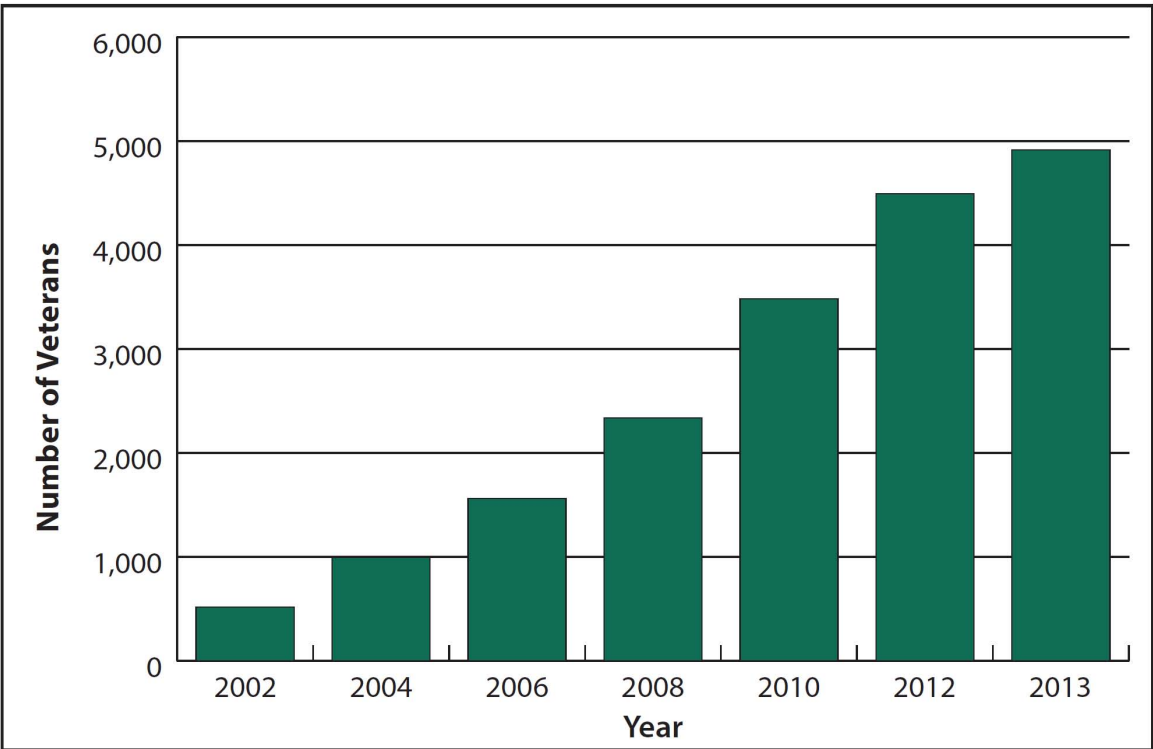
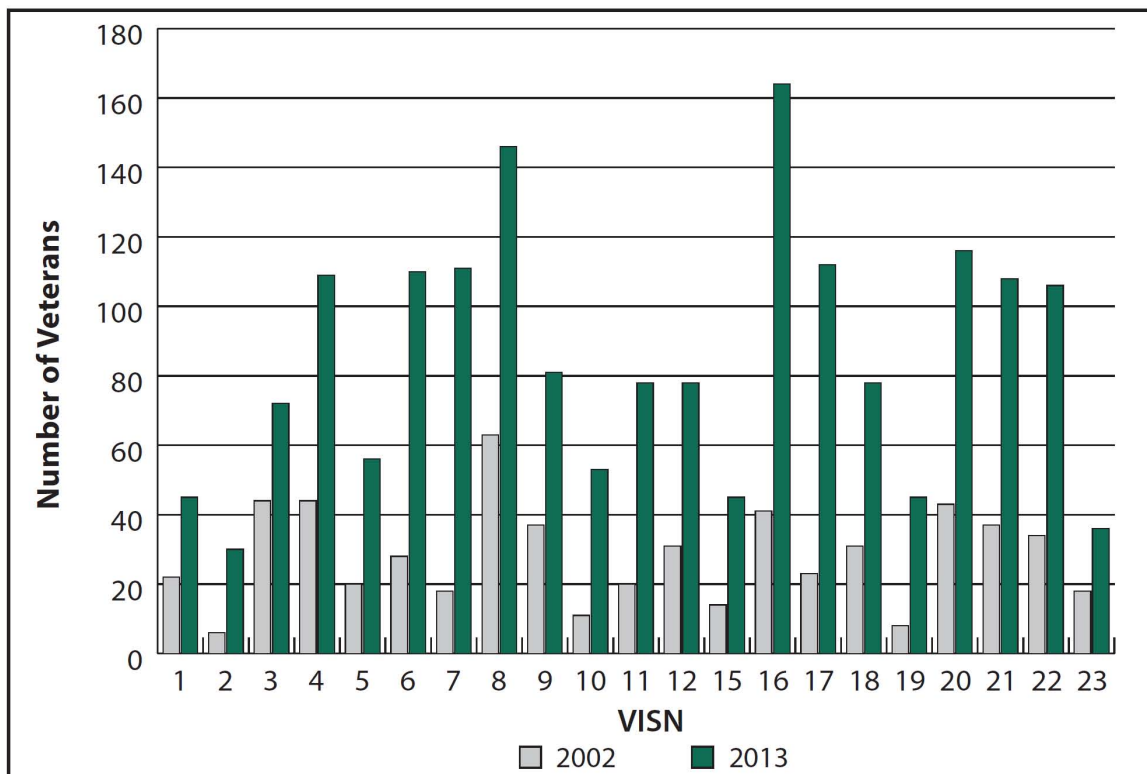


Figure 28. Number of HCV viremic Veterans in care who had ever received diagnosis of hepatocellular carcinoma: 2002-13



A comparison of the incidence of HCC among HCV viremic Veterans between 2002 and 2013 by VISN is shown in Figure 29. The number of new diagnoses of HCC in 2013 ranged from 30 in VISN 2 to 164 in VISN 16.

Figure 29. Number of HCV viremic Veterans in care with first VHA diagnosis of hepatocellular carcinoma during the target calendar year, by VISN: 2002 and 2013



Chapter 6: Current challenges and future directions

6.1 Current challenges

The data presented in this report underscore both the challenges and the opportunities related to care of Veterans with hepatitis C. As the largest single provider of care for HCV infection in the U.S., VHA is charged with addressing an epidemic of life-threatening complications among Veterans with HCV infection, with rising numbers of patients with cirrhosis and HCC. The challenge is increased by the likelihood that some Veterans with HCV infection remain undiagnosed. The window of opportunity available to confront these issues is narrow, making rapid responses imperative.

At the same time, the introduction of new, highly effective and less toxic anti-viral therapies that are easier to administer than older treatments holds the promise of eradicating this disease in affected Veterans. In addition, the synthesis of a population health approach to HCV infection with system redesign will improve access to high-quality HCV care for Veterans. Finally, the experience, expertise, and dedication of VHA providers will allow VA to deliver the excellent care that Veterans with hepatitis C deserve.

6.2 Future directions

The landscape of HCV treatment is changing dramatically with improved antiviral treatments available and more on the horizon. This fluid landscape is superimposed on the high burden of HCV infection among the nation's Veterans in VHA care. The majority of the 174,302 HCV viremic Veterans in care were exposed during the Vietnam War era. This cohort of Veterans has been infected with HCV for decades, and as a result, is at increased risk of cirrhosis and HCC. Improving clinical outcomes in patients with HCV infection – especially those with cirrhosis, who are at the highest risk of complications – depends on early identification of HCV-infected patients, efficient linkage to care, evidence-based interventions to reduce modifiable risks for disease progression, and use of effective treatments for HCV and its complications.

As the landscape shifts, HHPHP is steering several initiatives that address comprehensive HCV disease management with a strong focus on system redesign and implementation science.

6.2.1 System redesign

Paul Batalden, one of the founders of the field of health care quality improvement, famously observed that, “Every system is perfectly designed to get the results it gets.” Superior (or inferior) health care outcomes are rarely primarily due to errors in judgment, although these certainly play a role. Rather, access to, quality of, and efficiency of care are determined by systemic barriers and gaps that affect patient and provider behavior and actions. This is certainly true in HCV infection care. For example, use of teleconsultation platforms such as SCAN-ECHO has dramatically improved access to high-quality HCV infection care for Veterans living in rural or highly rural areas. As another example, treatment-limiting comorbidities such as depression or alcohol use affect both candidacy for antiviral treatment and progression of liver disease. System redesign initiatives that shift management of such comorbidities from a consult-driven system to an integrated care model dramatically improve rates of abstinence from substance use or alcohol, antiviral treatment initiation, medication adherence, and sustained viral response.

HHPHP is collaborating with a variety of stakeholders within VHA, such as the Veterans Engineering Resource Centers, the SCAN-ECHO Program, the QUERI-HIV/HCV and others to develop VISN-centered system redesign teams that will coordinate care of HCV and its complications across a wide area. Application of system redesign principles to HCV diagnosis, treatment, and care promises to substantially improve access to, quality of, and efficiency of care.

6.2.2 Increasing HCV treatment workforce capacity

A shortage of VHA providers trained to provide antiviral treatment to Veterans with HCV infection could constrain VHA's ability to take full advantage of new antiviral therapies that are more effective, less toxic, and easier to administer than interferon-based therapies. To address this, HHPHP has launched a number of initiatives, in collaboration with stakeholders inside and outside VHA that will increase VHA's system-wide capacity to deliver antiviral treatment to Veterans with HCV infection. These include:

- Collaboration with PBM and the VHA's Office of Nursing Services to train clinical pharmacists, nurse practitioners, and advanced practice registered nurses as providers of HCV antiviral treatment. This strategy is particularly promising, given published data showing that antiviral treatment by well-trained non-physician providers is as likely to result in cure as treatment by physicians (Backus, et al. 2014).
- Collaboration with the VHA Office of Specialty Care on SCAN-ECHO, which uses a successful case-based didactic model to train primary care providers to deliver antiviral treatment (Arora, et al. 2011).
- Lastly, although HCV treatment has traditionally been the domain of gastroenterologists and hepatologists, infectious disease physicians are well-suited to deliver HCV antiviral care because of their experience in providing antiretroviral therapy to patients with HIV infection and their familiarity with issues such as antiviral resistance and treatment adherence. Approximately 15% of HCV clinic directors in VHA are infectious disease physicians.

Thus, infectious disease specialists represent another pool of caregivers available to enlist in building HCV treatment workforce capacity in VHA. For example, at the West Haven VA Medical Center, a long-standing program in HCV infection care for infectious disease fellows, supported by the VHA Office of Academic Affiliations, provides formal training and experience in treating Veterans with HCV infection. Expansion of such programs and further involvement of infectious disease physicians in HCV treatment in VHA care has a strong potential for strengthening VHA's ability to deliver HCV antiviral treatment to patients.

6.2.3 The Hepatitis C Resource Center (HCRC) Program

A primary initiative of HHPHP is the continuation of the VHA Hepatitis C Resource Center (HCRC) Program, which has provided clinical leadership, products, and programs to assist practitioners in caring for HCV patients. The HCRC Program has also served as a field-based laboratory for developing and evaluating new clinical strategies related to HCV infection. The HCRC Program has developed a strong focus on system redesign and implementation science and evaluation, while disseminating nationally best practice innovations that have been developed locally or regionally over the past decade.

6.2.4 National HCV Treatment Considerations Workgroup

The importance of antiviral therapy in curing HCV infection and decreasing the risk of death from complications of HCV infections has been well-established, but the use of antiviral therapy was until very recently limited by the high toxicity and low cure rates of the available therapies. Recent FDA approval of more efficacious and less toxic HCV treatment regimens has rapidly expanded the population of patients who may safely receive therapy. In the next few years, numerous additional regimens are expected to receive FDA approval. HHPHP has organized a National HCV Treatment Considerations Workgroup of VHA experts in HCV care that critically analyzes clinical trials data and national HCV treatment guidelines in order to develop the VHA HCV Treatment Considerations document. The Treatment Considerations document will guide VHA providers in the use of these new and upcoming medications. This will be an ongoing workgroup, with the purpose of rapidly analyzing published clinical trials and disseminating updated guidance to VHA HCV providers as new and more effective treatments for HCV become available. The current version of the VHA HCV Treatment Considerations document is available at <http://www.hepatitis.va.gov/provider/guidelines/2014hcv/index.asp>.

6.2.5 Increasing capacity for treatment of mental health comorbidities among HCV-infected Veterans

A substantial proportion of Veterans with HCV infection have not previously been candidates for therapy because of the high prevalence of mental health, substance use, and alcohol use disorders in this population (Bini, et al. 2005). These conditions not only lead to morbidity and mortality in their own right, but can also limit safe administration of antiviral therapy for patients with HCV infection. In an era of interferon-free treatment regimens and high medication costs, it is more important than ever for patients with HCV infection to be identified, evaluated for treatment, and connected with resources to address these comorbidities, which may have implications for treatment adherence. Integrated care models promote access to mental health and substance use care, increase referrals for antiviral therapy for patients with these comorbidities, increase adherence, and result in treatment outcomes similar to those of patients without mental health and substance use disorders (Anand, et al. 2006; Dieperink, et al. 2010; Evon, et al. 2011; Ho, et al. 2008; Knott, et al. 2006). To this end, HHPHP has supported a postdoctoral training fellowship for psychologists in HCV and HIV clinical care. The expansion of this fellowship has educated mental health and liver providers about the high prevalence of mental health and substance use comorbidities among Veterans with HCV infection, as well as augmented the national availability of psychology professionals with dedicated training in evidence-based psychotherapy tailored for HCV and HIV-infected individuals.

In addition, HHPHP sponsors educational programs on care of Veterans with HCV and mental health comorbidities, including training in brief alcohol interventions for HCV patients with alcohol use disorders, creation of an addiction pharmacotherapy Community of Practice, and a seminar series on psychosocial evaluation of liver transplant candidates.

6.2.6 Universal screening of the 1945-65 birth cohort

Increased screening for HCV is a critical component of early identification and linkage to care. Joining CDC and USPSTF, in November 2013, the VHA Preventive Medicine Field Advisory Committee voted to approve a new Clinical Preventive Services Guideline recommending HCV screening for the 1945-65 birth cohort. VHA NCP released guidance in January 2014 recommending one-time screening for all Veterans within the 1945-65 birth cohort in addition to

all Veterans who have known risk factors. Education targeting health care system staff members who work in areas of high HCV prevalence (primary care, mental health, substance abuse, and homeless outreach programs) about the natural history of HCV infection, including the need for screening, is key to early identification, prompt referral, and linkage to appropriate HCV care. HHPHP has been actively engaged in the promotion of this new guidance, particularly promoting HCV screening among homeless Veterans. HHPHP is also collaborating with NCP on development of an electronic clinical reminder to improve already high rates of screening among Veterans in the 1945-65 birth cohort.

6.2.7 Advanced liver disease care

Effectively addressing HCC and other complications of HCV infection requires early diagnosis and referral for evaluation and care. Education of providers, particularly in primary care, about the diagnosis of HCC is a central part of improving clinical outcomes for patients with advanced liver disease, along with use of decision support tools such as clinical reminders. HHPHP is overseeing various projects to improve clinical surveillance rates and timely diagnostic evaluations for patients with suspected HCC. HHPHP's first *State of Care for Veterans with Advanced Liver Disease* report, based on data from the VHA National LDD (a quality improvement enterprise supported by HHPHP) will be invaluable in identifying system-wide needs for HCC detection, treatment, and gaps in care.

6.2.8 HCV Health Analysis and Information Group (HAIG) Survey

Understanding the variations in models of VHA care between VISNs and health care systems is key to standardizing quality care delivery. A revised and updated survey of clinicians providing HCV care across the system will be undertaken in the near future. Understanding variations, and identifying which approaches are used by high- and low-performing facilities, will help improve the quality of care.

6.3 Beyond Hepatitis C

Future work to improve the quality of HCV care will be based in large part on understanding of the variation in HCV care structures, processes, and outcomes between VISNs, as well as between individual VHA facilities. The information presented in this State of Care Report on antiviral therapy and on quality of care measures indicates the potential for learning more about which approaches are successful and which are not from those VISNs and facilities with high and low performance rates. Additional work will be required to more clearly understand care delivery at the local VHA healthcare system level. This will guide the design and execution of effective system redesign efforts, as well as dissemination and implementation of products and models of care designed to address specific quality issues. Such approaches may be exportable to other disease states or to other VHA facilities.

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Appendix A

VISN	Location
1	VA New England Healthcare System
2	VA Healthcare Network Upstate New York
3	VA NY/NJ Veterans Healthcare Network
4	VA Healthcare
5	VA Capitol Health Care Network
6	VA Mid-Atlantic Health Care Network
7	VA Southeast Network
8	VA Sunshine Healthcare Network
9	VA Mid-South Healthcare Network
10	VA Healthcare System of Ohio
11	Veterans in Partnership Healthcare Network
12	VA Great Lakes Health Care System
15	VA Heartland Network
16	South Central VA Health Care Network
17	VA Heart of Texas Health Care Network
18	VA Southwest Health Care Network
19	Rocky Mountain Network
20	Northwest Network
21	Sierra Pacific Network
22	Desert Pacific Healthcare Network
23	VA Midwest Health Care Network

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